BladderScan® BVM 9500

Bladder Volume and Mass Instrument

User's Manual

CAUTION: In the United States, federal law restricts this device to use by or on the order of a physician.

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Statement From the CEO

The team at Verathon is committed to improving health care delivery by putting healthcare providers and their patients first.

Our products support you, the health care provider, by consistently offering accuracy, utility, reliability and excellence.

Please contact us directly at 1.800.331.2313 (USA and Canada only) or 1.425.867.1348, if we can improve our service to you.

Sincerely,

Gerald McMorrow

Gerald McMorrow, CEO and Founder

Important Information

Product Description

The BladderScan BVM 9500 is a portable ultrasound instrument that provides noninvasive measurements of urinary bladder volume, bladder wall thickness and Ultrasound-Estimated Bladder Weight (UEBW). The device consists of an ultrasound Probe that scans the patient's bladder and a compact, battery-operated Console that provides an array of measurement-related information.

The BladderScan BVM 9500 is noninvasive and comfortable for the patient. It is quick, accurate, reliable, and easy to use. When the user releases the scan button, within seconds, the BVM 9500 measures ultrasonic reflections on multiple planes inside the body and produces a three-dimensional image. Based on this image, the BladderScan BVM 9500 calculates and displays the bladder volume, bladder wall thickness and UEBW. A sonographer is not required.

Patent-pending NeuralHarmonics® technology (abbreviated from "neural network harmonics") in the BVM 9500, sharpens accuracy and accelerates speed of bladder volume measurement. Volume measurements made with NeuralHarmonics technology are more accurate than those from conventional two-dimensional ultrasound, as they are based on a more complex, multifaceted image of the bladder. This technology, applying multi-spectral analysis to a robust data set, helps reduce margin of error and minimize uncertainty in essential measurements of bladder function.

If needed, after a scan has been taken, a unique aiming icon guides the operator to optimal Probe placement with a comprehensive display showing the bladder in two cross-sectional images verifying that a complete scan has been achieved. Bladder volume, patient type, directional aiming with real-time feedback, battery status, and usage rate indicators are all displayed on the device's LCD screen.

BladderScan BVM 9500 measurements can be printed via an onboard printer or transmitted using HIPAA-compliant ScanPoint® image management technology for storage and archiving on Verathon® servers. Stored exams can be accessed at any time from your office's computer for viewing or printing. (NOTE: Use of ScanPoint software is optional.)

Exam results may also be transmitted to a computer running ScanPoint with QuickPrint software via a proprietary wireless connection. ScanPoint with QuickPrint allows the user to archive data, calibrate the device, update software, print, and transfer data through a Web-based interface.

A Calibration Targeting System, consisting of a spiral-shaped calibration target along with a special calibration container, allows the user to easily calibrate the device by scanning a known target.

The BladderScan BVM 9500 system also includes a universal battery charger for the custom, user-replaceable Lithium Ion battery incorporated in the system. The BladderScan BVM 9500 may be mounted on a wheeled cart which holds the instrument securely and provides a holder for the Probe and a bottle of ultrasound gel.

Intended Use Warnings and Cautions

The BladderScan BVM 9500 should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All users must read this *User's Manual* prior to using the BladderScan BVM 9500. Do not attempt to operate this instrument until you thoroughly understand all instructions and procedures in this manual. Failure to comply with these instructions may compromise the performance of the device and the reliability of its measurements.

For the most current version of the *User's Manual*, please visit the Verathon Web site at: **http://www.verathon.com**.

Biological Safety

To date, exposure to pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, ultrasound should be used only by medical professionals when clinically indicated, using the lowest possible exposure times indicated by clinical need.

The ultrasound output power of the BladderScan BVM 9500 is not user adjustable and is limited to the minimum level necessary for effective performance. Data on acoustic output levels can be found in the *BladderScan BVM 9500 Instrument Specifications* section of this manual on page 70.

Statement of Prescription

United States federal law restricts the BladderScan BVM 9500 to use by, or on the order of, a physician. This statement is required per 21 Code of Federal Regulations (CFR) 801.109.

NOTE: It is standard practice to have medical staff authorize the use of the BladderScan BVM 9500 within its intended use throughout an institution. Individual prescriptions for use are not required.

Statement of Intended Use

The BladderScan BVM 9500 is intended to project ultrasound energy through the lower abdomen to obtain an image of the bladder and measure urinary bladder volume and mass noninvasively.

Contraindications

The BladderScan BVM 9500 is not intended for fetal use or for use on pregnant patients.

Cautions and Warnings

To assure safe and reliable operation for the use and the patient, please read and heed the following warnings and cautions.

WARNING! Risk of explosion.
If you use the BladderScan BVM 9500 in the presence of flammable anesthetics, the hazard of potential explosion exists.

WARNING! Risk of explosion, fire, or serious injury.
The BladderScan BVM 9500 is provided with two Lithium Ion batteries. Never short circuit the battery pack by either accidentally or intentionally bringing the battery terminals into contact with any other conductive object. This could cause serious injury or fire and could also damage the battery pack and the BladderScan device.

Never expose the battery pack to abnormal shock, vibration, or pressure. The main battery pack's internal protective covering could fail, causing it to overheat or ignite, resulting in caustic liquid leakage, or explosion or fire, possibly resulting in serious injury.

WARNING! Potential patient hazard.
To date, exposure to low-power, pulsed diagnostic ultrasound has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated, using the lowest exposure times possible to obtain accurate measurements. The ultrasonic output of the BladderScan BVM 9500 is not user-adjustable and is limited to the minimum level necessary for effective performance. For more information about the acoustic output levels of this device, please refer to the section in this manual titled *BladderScan BVM 9500 Instrument Specifications* on page 70.

CAUTION! Risk of inaccurate measurements/results.
When using the BladderScan BVM 9500 be aware of the following conditions which can affect ultrasound transmission and the accuracy of exam results.

- Use care when scanning patients who have had supra-pubic or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and accuracy.
- Do not use the BladderScan BVM 9500 on a patient with open skin or wounds in the suprapubic region or mid-abdominal area.
- Do not use the BladderScan BVM 9500 on a patient with ascites.
- If you scan a patient with a catheter in his/her bladder, the catheter may affect measurement accuracy. However, the information obtained from the measurement could still be clinically useful for detecting problems such as a blocked catheter.

CAUTION! Use the following procedure to reset your instrument if your BladderScan BVM 9500 suffers from a configuration loss and displays the Home screen for a BladderScan BVI 9400 instrument.

NOTE: Only use this process to restore the factory set configuration. Do NOT use this reset process for any other issue.

- In very rare instances, your instrument may experience a configuration file error.

- If a configuration file error occurs, the instrument will lose its factory set configuration and return to its default configuration as a BVI 9400 instrument, meaning it will display a BVI 9400 Home screen.
- To re-establish the factory configuration specific to your instrument, please follow these steps.

NOTE: Do not press the Power button at any time when the battery is removed.

To reset the factory set configuration:

1. Turn the Console OFF.
2. Turn the Console ON and wait for the Home screen to appear.
3. Remove the battery from the Console. Wait 30 seconds. **Do NOT press any buttons on the Console while the battery is removed**.
4. Re-insert the battery into the Console. Wait 30 seconds. If the Console does not turn on automatically, turn the Console ON.
5. Confirm that the instrument displays the correct configuration by checking the model number displayed in the upper left corner of the screen.

CAUTION! Observe the following precautions in the safe use and care of the BladderScan BVM 9500.

Hazardous materials present. Assure proper disposal.
The BladderScan BVM 9500 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan BVM 9500 has reached the end of its useful service life, return the device, charging cradle, and related accessories to a Verathon Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

Assure proper computer system configuration.
When using the BladderScan BVM 9500 with optional ScanPoint® software, your computer must be minimally certified to EN / IEC / CSA / UL 60950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Anyone connecting additional equipment to the BladderScan BVM 9500 signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with EN/IEC 60601-1-1. If you need assistance, contact your biomedical staff, Verathon Medical representative, or the Verathon Medical Customer Care Department at 1.800.331.2313.

Assure proper distance from patient.
The BVM 9500 battery charger/wireless hub and the computer used to access online ScanPoint image archives (if used) must be placed outside the patient vicinity (more than six feet (2 meters) from the patient). Refer to UL 2601-1 Clause 2 deviation for the definition of patient vicinity.

Bluetooth® Wireless Technology

NOTE: This feature is used only with the optional ScanPoint® software.

The *Bluetooth* technology used in the BladderScan BVM 9500 is compliant with:

- *Bluetooth* Specification as defined and approved by The Bluetooth Special Interests Group.
- Logo certification with *Bluetooth* wireless technology as defined by The *Bluetooth* Special Interest Group.

CAUTION! **Risk of Fire and Burns.** Regarding the battery, do not disassemble, heat above 60° C (140° F), or incinerate. Keep battery out of reach of children and in original package until ready to use. Dispose of used batteries promptly according to local recycling or waste regulations.

CAUTION! *Bluetooth* and Wireless LAN devices operate within the same radio frequency range and may interfere with one another. If you are using the BladderScan BVM 9500 *Bluetooth* link and Wireless LAN devices simultaneously, you may experience less than optimal network performance or even loose your network connection. If this happens, you may need to move the BladderScan instrument and ScanPoint host computer to an area away from the 2.4 GHz wireless LAN devices (40 meters/44 yards, or more).

Introducing the BladderScan BVM 9500

The BladderScan BVM 9500 is designed for simple, intuitive operation. However, to ensure safe and effective operation, before using the device:

- Familiarize yourself with the contents of this manual.
- Watch the training videos provided on the instrument and on the In-Service CD.

BladderScan BVM 9500 Parts and Features

The BladderScan BVM 9500 has two main components: The Console and the Probe. The Console and Probe are linked by a detachable cable. The BladderScan BVM 9500 controls and indicators are illustrated in Figure 1.

Figure 1. BladderScan BVM 9500 Controls and Indicators

Probe Components

The Probe transmits and receives ultrasound waves, automatically moving its internal Probe 360º to scan 24 different planes to produce a three-dimensional image of the bladder. The Probe is attached to the Console by a cable. The Probe has three main features:

Part Name	Purpose
SCAN button	Press to take a scan.
Aiming Display	The LCD displays directional arrows to assure that the bladder is centered within the scanning cone.
Microphone	Records voice annotations.

Console Components

The Console provides all operating controls for the scanning process by means of five variable function buttons. The measured bladder volume and UEBW and target-shaped aiming icons are clearly displayed on the LCD screen. The Console also provides controls for adjusting brightness and volume, turning the power on/off, interfacing with a ScanPoint®-equipped computer (optional), and adjusting user settings and preferences. The Console also houses the battery and the printer. The Console's controls and features are described in the following table:

Part Name	Purpose
Main Display	Displays the bladder volume measurement, patient type, settings, and instrument status.
Power ON/OFF	Toggles main power on/off
Volume	Press to adjust volume up/down on voice annotation playback, start up sound, and "scan complete" tone.
Brightness	Press to adjust display brightness dimmer/brighter.
5 Variable Function Buttons	Depending on device mode, the buttons provide access to all instrument functions for scanning, recording annotations, printing, connecting to ScanPoint (optional), accessing the training video, and setting user preferences.
Printer / Printer Door	Press to release the printer door.

Battery Charger/Wireless Hub

The BladderScan BVM 9500 is powered by a Lithium Ion (Li-Ion) battery pack. The battery charger provided with your BVM 9500 can charge two Li-Ion battery packs while simultaneously functioning as the wireless hub linking your BVM 9500 to the ScanPoint® host computer.

NOTE: Use of ScanPoint with QuickPrint software is optional.

- To provide power to the battery packs, the battery charger/wireless hub must be plugged into a wall outlet using the power cord provided.
- To provide wireless communication between the BVM 9500 and the ScanPoint host computer, plug the battery charger/wireless hub USB connector into a USB port on the ScanPoint® host computer.

The battery charger/wireless hub maintains an operating distance of up to 120 feet (36 meters) between the ScanPoint host computer and the BVM 9500, regardless of barriers such as walls, ceilings, or windows.

Figure 2. Battery Charger/Wireless Hub

Charging bays for two battery packs
Plug into wall outlet to power the battery charger
Plug into a USB port on the ScanPoint® host computer (optional) to enable a wireless connection with the BVM 9500

Parts and Accessories

Part Number	Description
0570-0207	BVM 9500 Console
0570-0208	BVM 9500 Probe
0570-0193	Battery Charger/Wireless Hub
0400-0066	Lithium Ion battery (2 provided)
0900-1596	BVM 9500 User's Manual (on In-Service CD)
0900-1601	ScanPoint® with QuickPrint User's Manual (on In-Service CD)
0900-2102	Quick Reference Card - BladderScan BVM 9500 Bladder Volume and UEBW Measurement
0900-1447	Quick Reference Card - Calibration
0800-0319	Thermal Paper Roll for the printer
0900-2103	BladderScan BVM 9500 In-Service CD (Includes User's Manuals, Video Tutorials, and Quick Reference Cards)
0800-0347	BladderScan BVM 9500 Medical Cart (optional)
0900-1238	ScanPoint with QuickPrint Software Install CD. **NOTE:** Use of the ScanPoint software is optional and not required for operation of the BVM 9500.
0620-0340	Calibration Kit (Optional - Requires ScanPoint with QuickPrint software. Includes Calibration Container, Calibration Target, etc.)
0800-0005	Acoustic Coupling Gel, 0.25 liter
0810-0201	Universal Accessory Basket for Medical Cart (optional)

Getting Started

The previous section provided basic information about the BladderScan BVM 9500 parts and features. This section provides instructions for setting up your BVM 9500 prior to first use.

To help you get up and running as quickly as possible, the next few pages explain how to:

- Unpack the BladderScan BVM 9500 and related accessories
- Charge and install the batteries
- Customize the display (enter your institution's name, date, time, and other user data)
- Assemble the Medical Cart (optional)
- Install the ScanPoint® with QuickPrint software (optional)

Unpack the Box and Check the Components

Set the shipping container right side up and carefully open the top flaps (do not insert anything sharp through the top of the box). Remove the contents and verify that you have received everything listed below. If anything is missing or damaged, notify your authorized Verathon Medical representative or Verathon Medical Customer Care Department at 1.800.331.2313.

(1) BladderScan BVM 9500 (Console and Probe)

(1) Medical Cart (optional)

(2) Rechargeable Lithium Ion batteries

(1) Battery Charger/Wireless Hub

(1) In Service CD (includes User Manuals, Video Tutorial, and Quick Reference Cards)

Charge the Batteries

Two Lithium Ion batteries are included with the BladderScan BVM 9500. One battery can be recharged in the battery charger/wireless hub while the other is installed in the BladderScan instrument. This ensures that there is no instrument downtime. The charger will bring the batteries to a full charge within 6 hours or less.

NOTE: Before using the BladderScan BVM 9500 for the first time, you will need to charge both batteries.

To charge the batteries:

1. Plug the battery charger/wireless hub unit into a standard wall outlet.
2. Remove the label covering the battery contacts and insert the battery into the recess in the battery charger

   NOTE: Fully charging the battery may take up to 6 hours.

   Batteries may be stored in the charger. There is no danger of overcharging the batteries.
3. Check the colored indicator lights on the battery charger to determine battery status:
   - **Solid green:** Battery fully charged.
   - **Amber:** Battery charging.

Install a Battery Pack in the Console

Warning! Risk of serious injury.
If the battery pack is leaking or its case is cracked, put on protective gloves to handle it and discard it immediately. Always dispose of used battery packs in compliance with all applicable laws and regulations. Put insulating tape, such as cellophane tape, on the electrodes during transportation to avoid a possible short circuit, fire, or electrical shock. Failure to do so could result in serious injury.

To insert a battery pack:

Insert the charged battery into the battery well in the Console, slide it under the ledge and push down gently until the battery clicks into place.

NOTE: The battery pack is designed to prevent incorrect installation. If the battery pack does not slide into the battery well easily, move the battery and try again. Do not force the battery into position.

NOTE: Do NOT remove the battery for any reason while the BVM 9500 is on. Doing so will damage the instrument. Always turn off the BVM 9500 before removing the battery.

Battery Care

The BladderScan BVM 9500 draws very little power when it is turned off. However, if you do not plan to use the BladderScan instrument for several weeks, you should remove the battery to prevent it from discharging.

When batteries are not in use, they should be stored in the battery charger so they remain fully charged.

Enter the Clinic Name

You can customize your BladderScan BVM 9500 by entering your facility's name and current date and time. This information will subsequently be included on BladderScan® displays and all printouts of exam results.

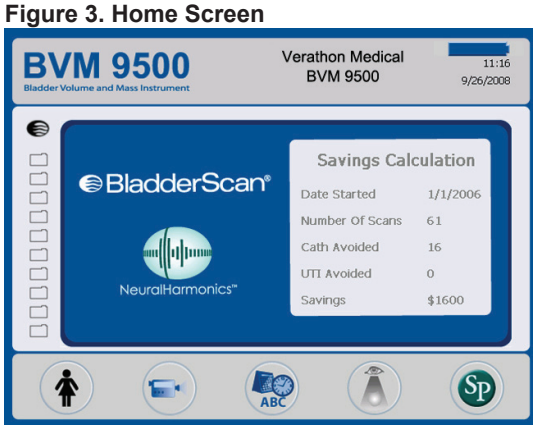
NOTE: Use of extended-Latin and/or non-Latin characters: The following instructions explain how to enter a facility name that uses only standard Latin characters. Extended-Latin characters (tilde, umlaut, accents, circumflex, etc.) and/or non-Latin characters can be entered only by using ScanPoint® with QuickPrint software. To enter a name that uses extended or non-Latin characters, please refer to the instructions in the ScanPoint with QuickPrint User's Manual.

To enter your clinic's name:

1. Turn the BladderScan BVM 9500 on by pressing the POWER button on top of the Console.

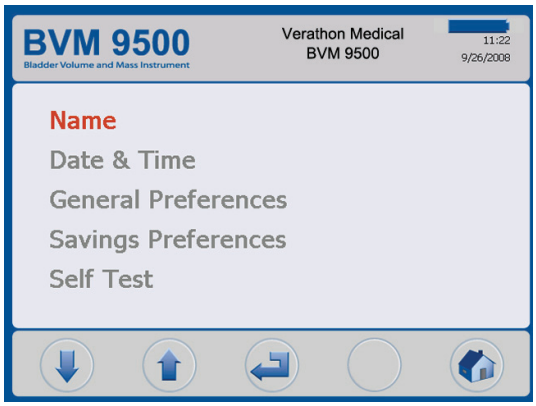
2. When the Home screen appears (Figure 3), press the SETTINGS button to open the Settings screen.

Figure 3. Home Screen



3. On the Settings screen (Figure 4), push either the or button until **Name** is highlighted (red). Press the button to open the Alpha-Numeric screen.

Figure 4. Settings Screen



4. On the Alpha-Numeric screen (Figure 5), use the ➔ and ➧ buttons to move to the desired character. When the desired character is highlighted (red), press the ✚ button to add it to your text. Use the - button to delete characters.
   - To add a space between words, press the blank space below the letter "**x**".
   - To add a second line of text use the ¶ character.
5. Continue to select and add characters as needed.
6. When finished, press the SETTINGS button to return to the Settings screen. From the Settings screen, press the HOME button to return to the Home screen. The facility name will now appear in the display header (Figure 6).

Figure 5. Alpha-Numeric Screen

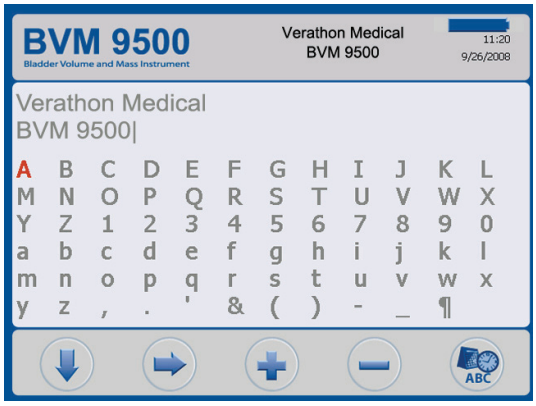
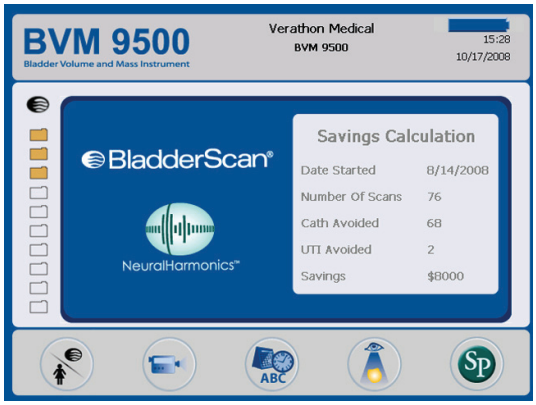

BVM 9500
Bladder Volume and Mass Instrument
Verathon Medical
BVM 9500
11:20
9/26/2008
Verathon Medical
BVM 9500|
A B C D E F G H I J K L
M N O P Q R S T U V W X
Y Z 1 2 3 4 5 6 7 8 9 0
a b c d e f g h i j k l
m n o p q r s t u v w x
y z , . ' & ( ) - _ ¶
ABC

Figure 6. Facility Name in Display Header



Set the Date and Time

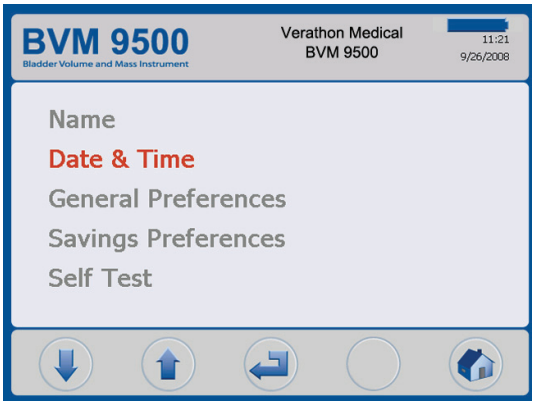
The clock can hold the current time and date setting for up to five minutes after the battery is removed. Time and date settings will be lost if the battery is removed from the instrument for longer than five minutes.

To set the date and time:

1. If the BladderScan instrument is turned off, turn the power on by pressing the ⏻ button on the front of the Console.
2. From the Home screen (Figure 3), press the SETTINGS button to open the Settings screen.

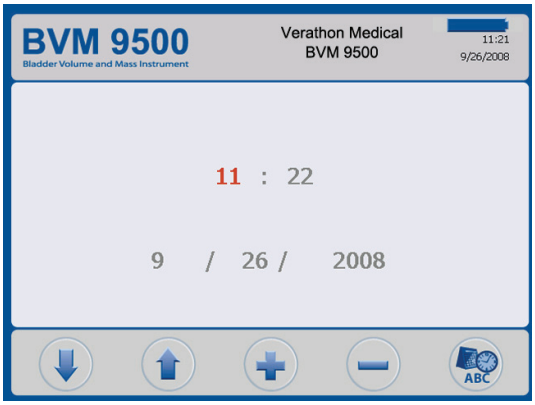
3. On the Settings screen, push either the ↑ or ↓ button until **Date & Time** is highlighted (red) (Figure 7). Press the ↵ button to open the Date & Time screen.
4. On the Date & Time screen (Figure 8), use the → and ↓ buttons to move to the desired unit (hours, minutes, month, day, year).

Figure 7. Set Up Screen - Date and Time



5. When the desired unit is highlighted (red),
   - Press the + button to increase values.
   - Press the - button to decrease values.
6. When the time and date are set correctly, press the SETTINGS button ABC to return to the Settings screen. From the Settings screen, push the HOME button to return to the Home screen.

Figure 8. Date and Time Screen



Setting General Preferences and Savings Preferences

NOTE: See page 39 for information about setting General Preferences, Savings Preferences, and Self-Test Options.

General Preferences, Savings Preferences, and Self-Test Options can be accessed from the Settings screen.

General preferences include options for: Language, Date Format, Time Format, Calibration Warning, Print Report Type, Print UEBW and Manual Wall Thickness Mode.

Savings Preferences include: UTI Rate, UTI Cost, Catheterization Cost, Catheterization Volume, Currency, and Savings Calculation.

Load a Roll of Thermal Paper

To load a new roll of thermal paper:

1. Open the paper compartment door (located on the base of the Console, under the display).
2. Slide the door to the right, then lift the printer door up.
3. Insert the end of a new paper roll with the thermal side down, into the paper slot.

   To verify which side is the thermal side, scratch the paper with your finger nail. If a black mark appears, this is the thermal side.

4. Extend the end of the paper past the end of the unit.
5. Rotate the printer door down. Make sure you hear it snap into place.
6. Slide the printer door to the left.
7. Tear the excess paper off.

CAUTION! To avoid paper jams, never fold the end of the paper roll or cut it diagonally or to a point.

NOTE: If the paper appears to be stuck in the printer, open the printer door on the back of the Console and clear the paper jam.

Assemble the Medical Cart (Optional)

NOTE: The Medical Cart (Figure 9) is an optional accessory. If you're not using the Medical Cart, please skip to the next section, Install the ScanPoint® with QuickPrint Software, on page 26.

Figure 9. Medical Cart, PN: 0800-0347

Medical Cart Parts List

Item No.	Quantity	Part Number	Description
1	1	0142-0289	Tray Assembly
2	1	0810-0140	Bracket and Post
3	1	0810-0002	Medical Cart Base
4	4	0261-0107	Screw PH W Lock 25-20 x 1/2
5	1	0260-0357	Fluted Knob 3/8-16 x 1.00
6	4	0810-0142	Caster, 3 inch
7	1	0810-0143	Caster, 3 inch with Brake
8	2	0136-0109	Loctite® 680

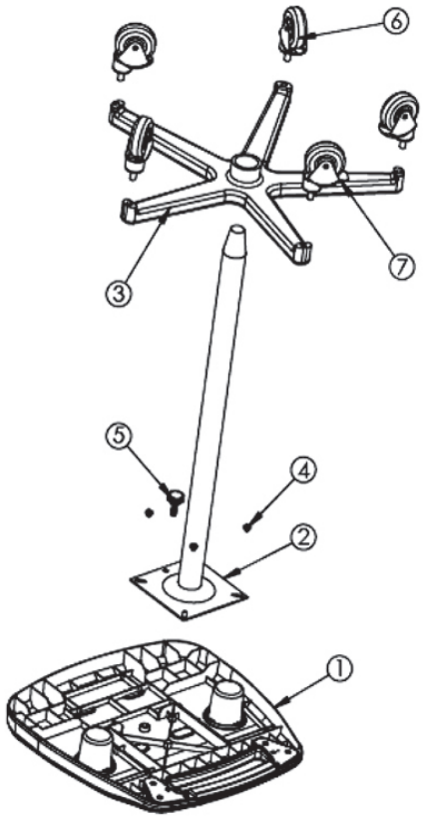
To assemble the cart:

Please refer to Figure 10 during assembly process

1. Align and press one 3-inch Caster with Brake (Item 7) and four 3-inch Casters (Item 6) into Medical Cart Base (Item 3).
2. Align through round hole in Bracket and Post (Item 2) bracket to through hole in Tray Assembly (Item 1).
3. Insert the Bracket and Post (Item 2) into the square relief in bottom of the Tray Assembly (Item 1).
4. Insert four Screws (Item 4) through the Bracket and Post (Item 2) into the molded inserts in the Tray Assembly (Item 1); tighten securely.
5. Place the Tray Assembly with the Bracket and Post into the Medical Cart Base (Item 3).

   NOTE: If permanent attachment of the Tray Assembly and Post to the Medical Cart base is required, refer to the Loctite® Option below before inserting the post into the base.
6. Place the BVM 9500 into the foot prints on top of the Tray Assembly (Item 1).
7. Screw the Fluted Knob (Item 5) through the Bracket and Post (Item 2) bracket round hole and hand tighten.

Figure 10. Medical Cart Assembly

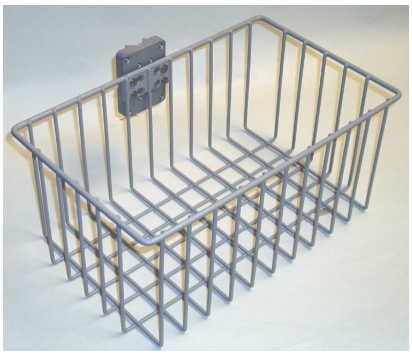


Loctite® Option

1. Place the medical cart base on a level floor.
2. Open 2 tubes of Loctite® 680 by snapping off the tip of the tube.
3. Apply the Loctite® 680 all around the tapered portion of the post. Use all of the contents of both tubes. Complete coverage of the taper is not necessary as the Loctite® will spread upon insertion into the base.
4. Slide the post into the hole in the base with a twisting motion and press down firmly.
5. Wipe off excess any Loctite® with a paper towel and discard towel as waste.
6. Allow the post and base to sit undisturbed for 3 hours.

A universal accessory basket (P/N 0810-0201) is available for the Medical Cart to add additional storage capacity (Figure 11).

Figure 11. Universal Accessory Basket P/N 0810-0201 (Optional)



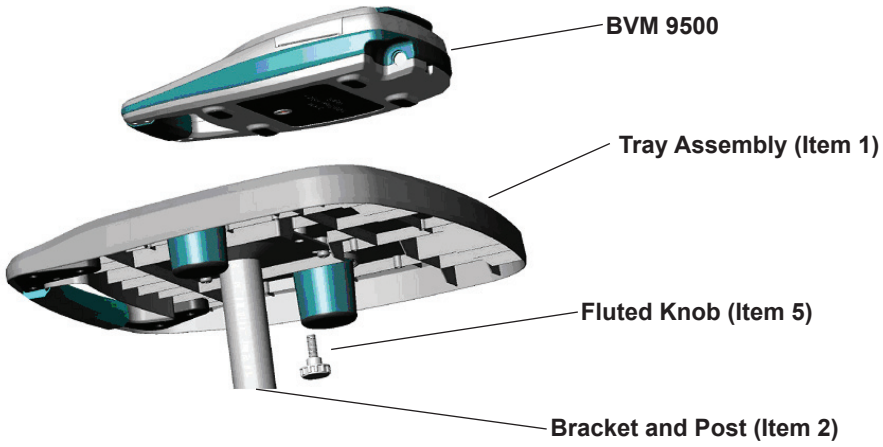
Install the BladderScan BVM 9500 on the Medical Cart (Optional)

Your BladderScan BVM 9500 is completely portable and can be easily moved and positioned for convenient use. Installing the BVM 9500 on the optional Medical Cart will allow you to move the BladderScan instrument along with related accessories (ultrasound gel or an extra roll of paper) to the patient examining area or bedside as necessary.

To install the BladderScan BVM 9500 on the Medical Cart:

To install the BVM 9500 to the Medical Cart, screw the Fluted Knob (Item 5) through Bracket and Post (Item 2) bracket round hole and Tray Assembly (Item 1), and into the mounting hole on the bottom of the device. Hand tighten (Figure 12).

Figure 12. Attaching the BVM 9500 to the Medical Cart



Install the ScanPoint® with QuickPrint Software (Optional)

Optional ScanPoint with QuickPrint software is designed to mesh seamlessly with your BladderScan devices. The BVM 9500 downloads exam data to the ScanPoint host computer via a wireless connection enabled by the battery charger/wireless hub - allowing further viewing, analysis, archiving, and report generation.

To install ScanPoint with QuickPrint, insert the ScanPoint with QuickPrint Install CD into your computer's CD drive and follow the on-screen prompts. Please refer to the separate User's Manual provided with ScanPoint with QuickPrint for complete installation and operating instructions.

Watch the Training Video

A training video provides an overview of how to perform an ultrasound scan of the bladder using the BladderScan BVM 9500. The video is approximately 5 minutes long.

The Measuring Bladder Volume and UEBW training video is available for review any time on the BladderScan BVM 9500 by pushing the button on the Home screen. The training video is also available for viewing on the BladderScan BVM 9500 In-Service CD.

The training video may also be found at **www.verathon.com**.

Displays, Controls, and Indicators

Console Displays and Button Functions

This section describes BladderScan BVM 9500 displays and button functions.

The Console display presents information that varies depending on the current instrument function.

The functions of the five buttons below the display vary according to current instrument mode and function. Button functions are indicated by icons in the display footer, immediately above the each button.

Battery Status Indicator

A battery status indicator appears in the header of all BVM 9500 screens. Depending on current level of battery charge, one of the following symbols will be displayed:

Indicates a fully charged battery.

Indicates a battery 50% to 75% charged.

Indicates a battery 25% to 50% charged.

Indicates a battery that is nearly discharged and can power only a few more scans.

Indicates the battery must be changed.

Home Screen

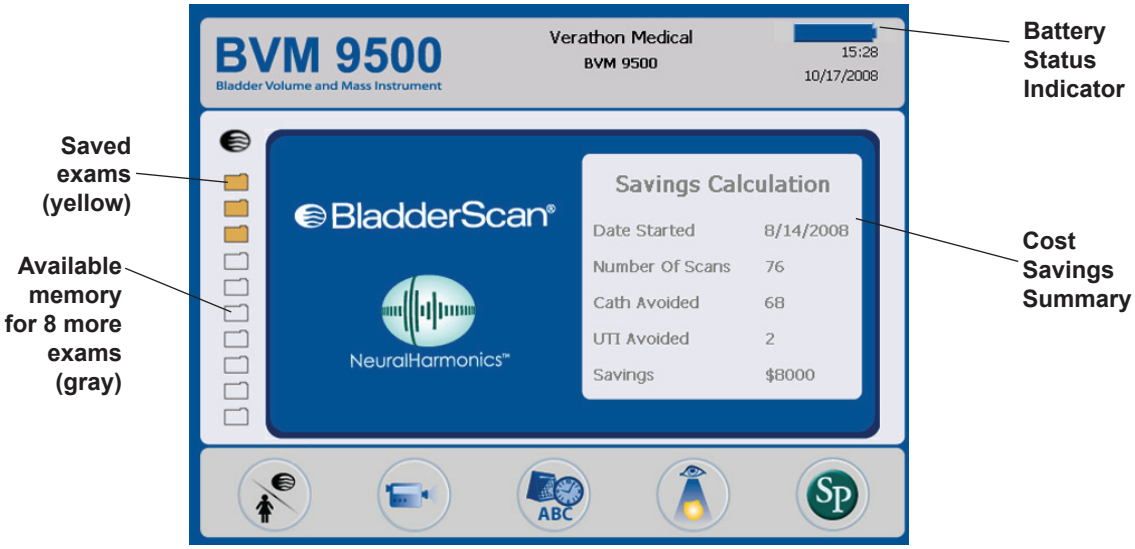
The Home screen appears when the BVM 9500 is first powered on. The Home screen serves as a starting point for all of the instrument functions.

Press the MODE button to toggle between Male and Female modes.

The Bladder Volume Mode home screen displays:

- A list of saved exam results (10 maximum) saved in chronological order. Yellow folders hold saved exams. Gray folders represent empty spaces still available for saving exam results.
- A Cost Saving Summary
  Displays the savings to your organization from using the BladderScan BVM 9500 rather than catheterization. The values used to determine the savings are user-variable and entered from the Savings Preferences Screen (Refer to page 42 for more information about using this screen).

Figure 13. Home Screen: Bladder Volume Mode



Home Screen Buttons

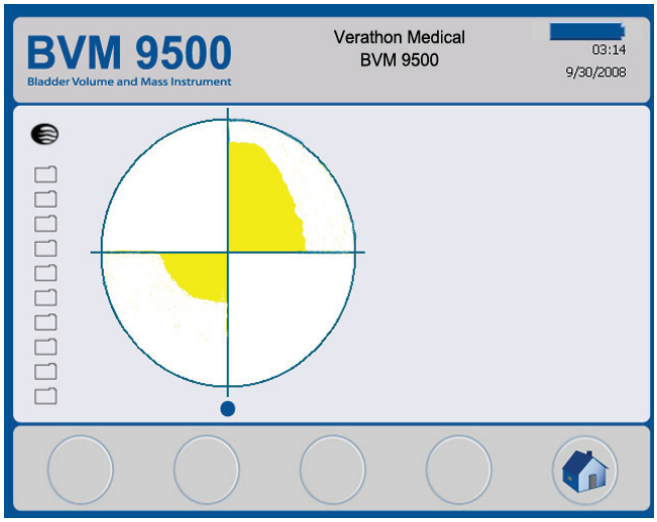
Button	Function
	Press to toggle between two possible scan options:
	◆ Take a bladder volume measurement of a female patient who has not had a hysterectomy. (When the female icon is illuminated, the BVM 9500 will assume the patient has a uterus.)
	◆ Take a bladder volume measurement of a male patient, or a female patient who has had a hysterectomy.
	Press to view the training video.
	Go to the Settings screen (set the time, date, institution name, and user preferences).
	Press to review a previously saved exam. (This button will be gray (inactive) if there are no previously saved exams to review.)
	Press to initiate communication with the ScanPoint® host computer. Saved and annotated exams will be automatically uploaded to the host computer. (ScanPoint® software must be previously installed and a connection open. Use of the ScanPoint® software is optional.)

Scan Screen

The Scan screen (Figure 14) appears and displays a progressively updating image of the bladder outline. When the ultrasound measurement is complete, the Results screen opens automatically.

The five buttons below the display do not function during the scan.

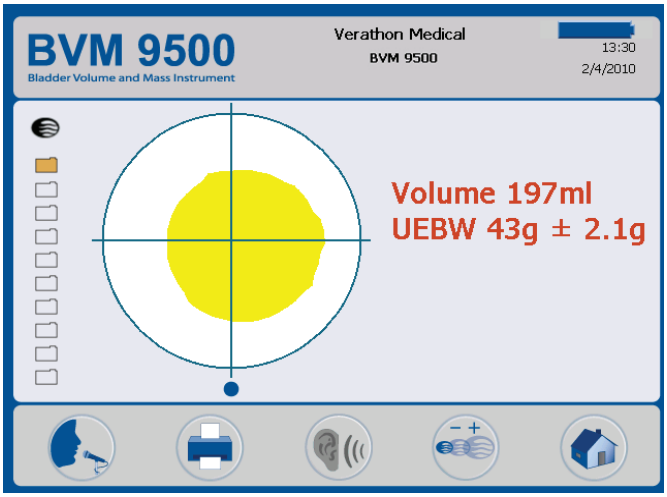
Figure 14. Scan Screen



Results Screen

The Results screen (Figure 15) appears automatically when a scan is complete. The Results screen displays the bladder outline, the calculated bladder volume and the ultrasound-estimated bladder weight (UEBW).

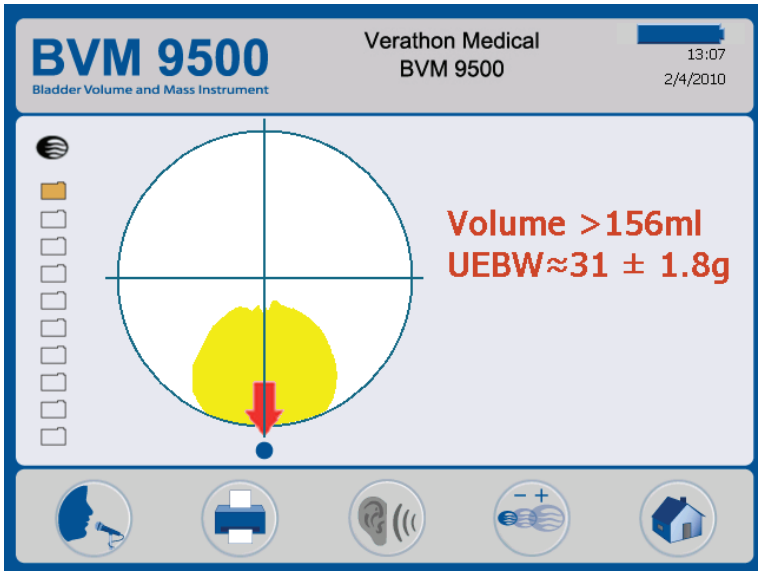
Figure 15. Results Screen



In Figure 15, a standard deviation value indicating the UEBW measurement confidence is displayed as a +/- range.

In some cases, the UEBW measurement will be expressed as an approximate value, using a ≈ symbol (Figure 16). This means that the measurement is an approximate result only and you should re-aim and re-scan to get a more accurate reading. The table below provides guidance on interpreting data displayed on the Results Screen.

Figure 16. Results Screen with Approximate UEBW value



Interpreting Results Screen UEBW Measurement Data

Aiming Arrow Present?	UEBW measurement symbol	Recommended Action
No	=	Accept UEBW measurement
No	≈	Adjust Probe pressure and/or Probe angle and scan again. Depending on patient anatomy, it may not be possible to get an = sign.
No	>	Bladder volume is too large for UEBW measurement
Yes	≈	Angle Probe in direction of arrow on Probe screen, or move Probe no more than 1/2 inch (1 cm) in direction of arrow; scan again
Yes	>	Angle Probe in direction of arrow on Probe screen, or move Probe no more than 1/2 inch (1 cm) in direction of arrow; scan again

Results Screen Buttons

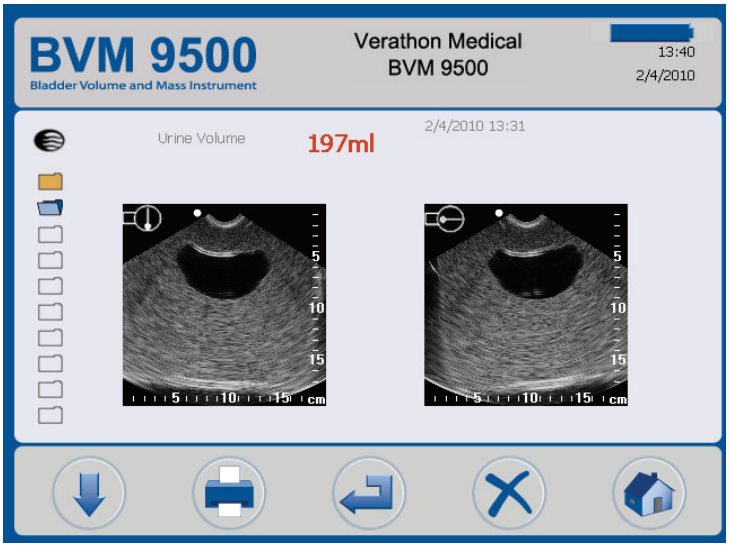
Button	Function
	Press to record a voice annotation (up to 10 seconds long).
	Press to print exam results
	Press to play a previously recorded voice annotation (blue). If no voice annotations are recorded, this button is disabled (gray).
	Press to go to the Image Zoom screen.
	Press to return to the Home screen.

Review Screen

The Review screens (Figures 17 and 18) open when you select a saved exam (blue folder icon) to review.

The displays shows the ultrasound images associated with the selected exam. A green open-folder icon indicates which exam is being viewed. While reviewing saved exams, the buttons below the display allow you to print, replay, or delete exam data

Figure 17. Review Screen 1

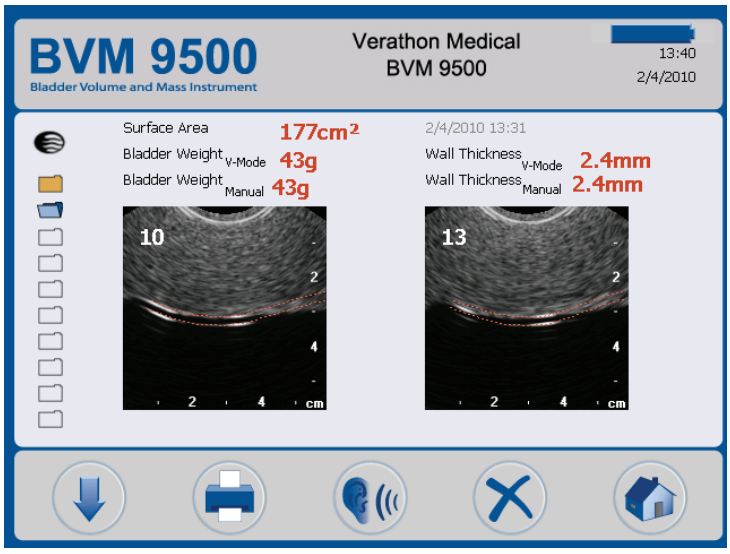


Review Screen 1 Buttons

Button	Function
	Press to select the next exam in the list.
	Press to print the results for the currently selected exam on the onboard printer. While printing is in progress an hourglass icon appears on the display.
	Press to view review additional data, including bladder surface area, UEBW, and bladder wall thickness (Review Screen 2).
	Press to delete the currently selected exam.
	Press to return to the Home screen.

Select the RETURN button on Review Screen 1 to view Review Screen 2 with bladder wall images (Figure 18).

Figure 18. Review Screen 2



Review Screen 2 Buttons

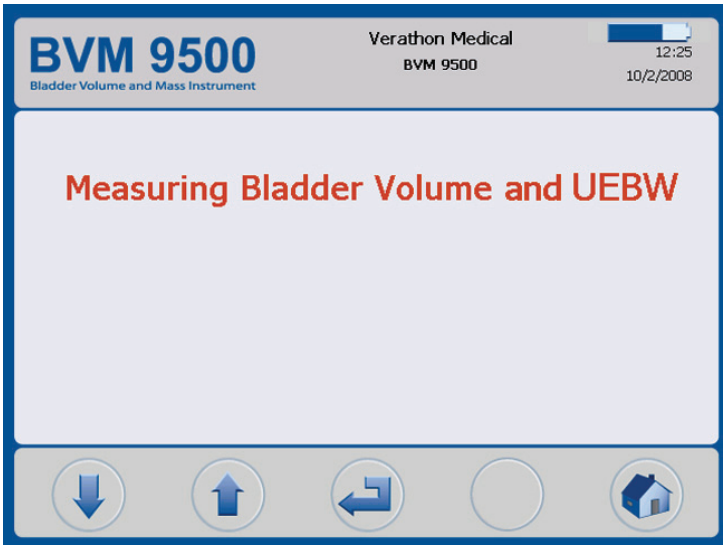
Button	Function
	Press to select the next exam in the list.
	Press to print the results for the currently selected exam on the onboard printer. While printing is in progress an hourglass icon appears on the display.
	Press to view review additional data, including bladder surface area, UEBW, and bladder wall thickness (Review Screen 2).
	Press to delete the currently selected exam.
	Press to return to the Home screen.

Tutorial Screen

To open the Tutorial Screen (Figure 19) press the button from the Home screen. The Tutorial screen presents a menu of training modules. To select a title, press either the or button until the desired title is highlighted (red). Press the button to go to the Video Viewing screen.

NOTE: The SCAN button (on the Probe) is disabled during module playback.

Figure 19. Tutorial Screen



Tutorial Screen Buttons

Button	Function
	SELECT NEXT: Press to move to next title.
	SELECT PREVIOUS: Press to move back to previous title.
	ENTER: Press to begin module playback. While the module is playing, press to pause. Press again to resume play.
	No function.
	HOME: Press to return to the Home screen.

Video Viewing Screen

The Video Viewing screen (Figure 20) is activated by pushing the ▶ button on the Tutorial screen (Figure 19).

NOTE: The SCAN button is disabled during video playback.

Figure 20. Video Viewing Screen

Video Viewing Screen Buttons

Button	Function
	No function.
	PLAY/PAUSE: Press to start video playback. Press to pause. Press again to resume play.
	BACK: Return to the training titles screen.
	No function.
	HOME: Press to return to the Home screen.

Settings Screen

To open the Settings screen (Figure 21), push the SETTINGS button on the Home screen.

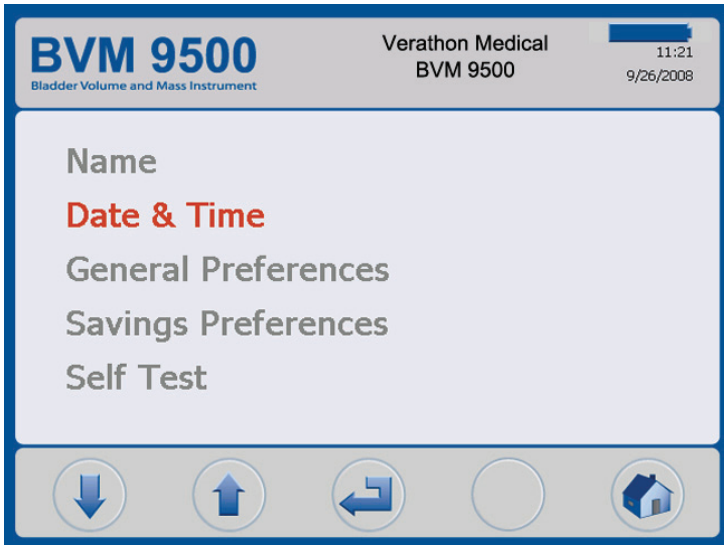
The display presents a list of user-configurable settings:

- Name (see page 37)
- Time & Date (see page 38)
- General Preferences (see page 39)
- Savings Preferences (see page 42)
- Self-Test (see page 43)

Use the Up/Down arrows to move through the list of options. To select an option, press the ENTER button.

NOTE: When any Settings screen is open, the SCAN button (on the Probe) is disabled.

Figure 21. Settings Screen Start Menu



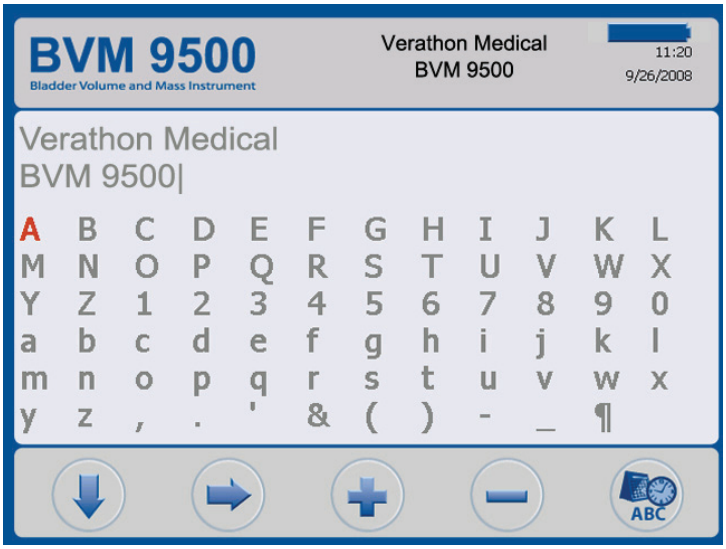
Settings Screen Buttons

Button	Function
	SELECT NEXT: Press to select the next setting in the list.
	SELECT PREVIOUS: Press to select the previous setting in the list.
	ENTER: Press to select the highlighted setting.
	No function.
	HOME: Press to return to the Home screen.

Alpha-Numeric Screen

This screen allows you to select the appropriate alpha-numeric characters for entering your health care institution's name.

Figure 22. Alpha-Numeric Screen


BVM 9500
Bladder Volume and Mass Instrument
Verathon Medical
BVM 9500
11:20
9/26/2008
Verathon Medical
BVM 9500|
A B C D E F G H I J K L
M N O P Q R S T U V W X
Y Z 1 2 3 4 5 6 7 8 9 0
a b c d e f g h i j k l
m n o p q r s t u v w x
y z , . ' & ( ) - _ ¶
ABC

Alpha-Numeric Screen Buttons

Button	Function
	Press to move down in the grid.
	Press to move to the right in the grid.
	Press to add the highlighted character to the name.
	Press to delete one character from the name.
	Press to return to the Settings screen.

Date & Time Screen

This screen allows you to adjust the date and time.

NOTE: If the time display is set to show a 24-hour clock, the hour units are 0 - 23. If the clock is set to show a 12-hour clock, the hour units are 1 AM - 12 AM and 1 PM - 12 PM.

Referring to the example shown in Figure 23:

To change the time from 20:42 AM to 23:30 (11:30 PM):

1. Press the ↓ button until the **20** is highlighted (red).
2. Press the + button 3 times until the time digits display **23:30**.
3. Press the ↓ button until the **42** is highlighted.
4. Press the + button repeatedly until the minutes display **30**.

   The time setting is now 23:30.
5. Press the SETTINGS button ABC to save this entry and return to the Settings screen.

Figure 23. Date & Time Screen

Date & Time Screen Buttons

Button	Function
	Move forward one changeable unit (e.g. hours, minutes, AM/PM, etc.).
	Press to move back one changeable unit.
	Press to add and/or toggle digits as appropriate (hours, minutes, AM/PM, months, day, years). Press and hold the button to move through options more quickly.
	Press to subtract or toggle digits as appropriate (same as above). Press and hold the button to move through options more quickly.
	Press to save the current date/time setting and return to the Settings screen.

General Preferences Screen

This screen displays a list of available settings and their current values.

Available settings:

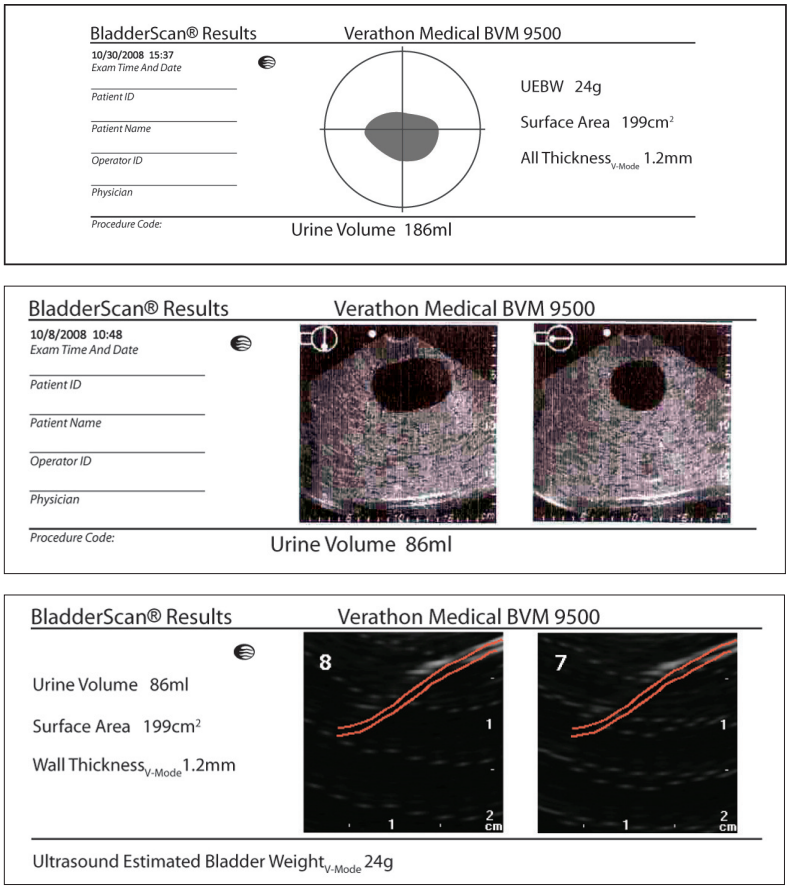
- **Language:** English (default), Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Italian, Hungarian, Japanese, Korean, Norwegian, Portuguese (European), Spanish, Swedish, Turkish.
- **Date Format:** mm/dd/yyyy; dd.mm.yyyy; yyyy-mm-dd.
- **Time Format:** 12-hour or 24-hour
- **Calibration Warning:** On (default), Off. When “On” is selected, a calibration warning will appear in the display header when the device requires calibration.
- **Print Report Type:** Toggle between C-Mode images (bladder in crosshairs) and B-Mode images (image of bladder and abdominal space below Probe). Figure 25 shows examples of C-Mode and B-Mode print reports, respectively.
- **Print UEBW:** Toggle between On/Off. When “On” is selected, any printout will include both Bladder Volume and UEBW measurements. When “Off” is selected, only Bladder Volume measurements will be printed. Figure 25 shows an example of the UEBW print report.
- **Manual Wall Thickness Mode:** Normal (default), Detrusor. When “Normal” is selected, manual wall thickness mode allows measurement of the entire bladder wall. When “Detrusor” is selected, manual mode allows measurement of the thickness of the detrusor muscle only.

Figure 24. General Preferences Screen

General Preferences Screen Buttons

Button	Function
	SELECT PREVIOUS: Press to select the previous setting in the list.
	SELECT NEXT: Press to select the next setting in the list.
	For settings with a list of options, press to select the next option.
	For settings with a list of options, press to select the previous option. Press and hold to move through options more quickly.
	Press to return to the Settings screen.

Figure 25. Print Report Samples



C-Mode Print Report Sample

B-Mode Print Report Sample

UEBW Print Report Sample

Savings Preferences Screen

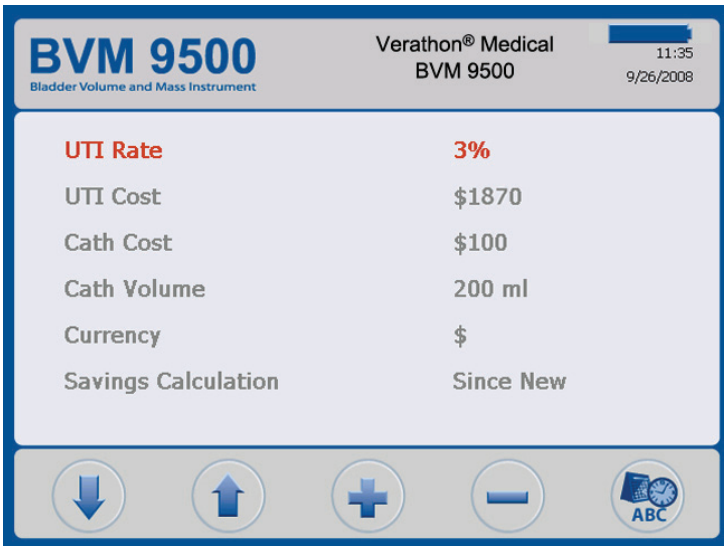
To open the Savings Preferences screen, select Savings Preferences from the Settings Screen (Figure 21, page 36).

Use this screen to enter base values used to calculate the savings to your organization from using the BladderScan BVM 9500 rather than catheterization.

Preferences lists and options:

- **UTI Rate:** 1% to 100% in increments of 1%
- **UTI Cost:** $10 to $10,000 in increments of $10
- **Catheter Cost:** $1 to $1000 in increments of $1
- **Catheter Volume:** 20 ml to 1000 ml in increments of 20 ml
- **Currency:** $ / € / £ / ¥
- **Saving Calculation:** Since New, Since 1/1/2006, Reset Now, Print Since New, Print Recent, Hide Savings
  - Select “Reset Now” to clear all savings preferences.
  - Selecting “Print Since New” or “Print Recent” and then ABC prints the Savings Calculation data.

Figure 26. Savings Preferences Screen



Savings Preferences Screen Buttons

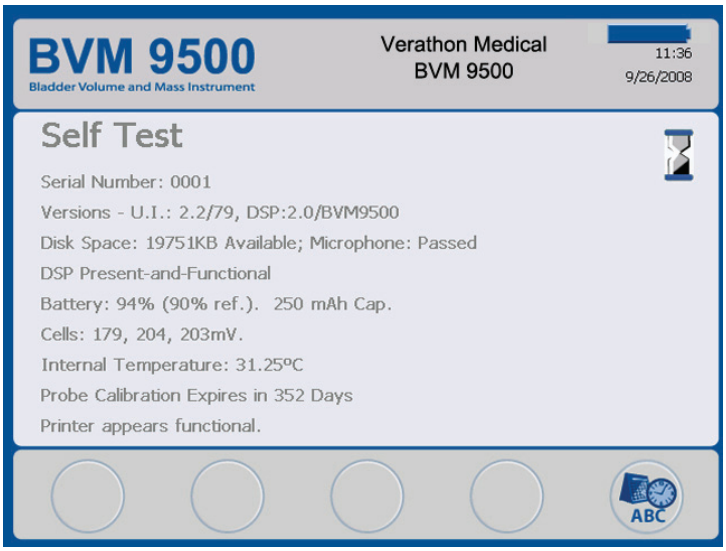
Button	Function
	SELECT PREVIOUS: Press to select the previous setting in the list.
	SELECT NEXT: Press to select the next setting in the list.
	For settings with a list of options, press to select the next option. Press and hold to move through options more quickly.
	For settings with a list of options, press to select the previous option. Press and hold to move through options more quickly.
	Press to save the current date/time setting and return to the Settings screen.

Self-Test Screen

To open the Self-Test screen, select Self-Test from the Settings menu (Figure 21, page 36). The Self-Test screen will open and testing begins automatically.

Press to return to the Settings menu.

Figure 27. Self-Test Screen



ScanPoint® Screen

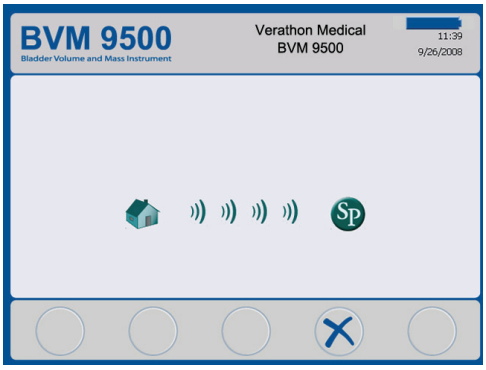
NOTE: Only available if optional ScanPoint software is installed on a PC.

To open the ScanPoint screen, press from the Home screen. The ScanPoint screens display information about the status of the link between the BladderScan instrument and the ScanPoint host computer (Figure 28).

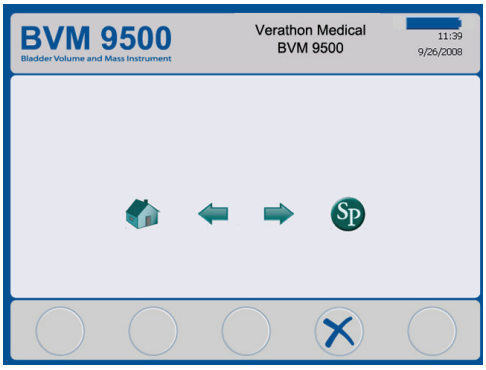
Press to terminate communication with ScanPoint.

Figure 28. ScanPoint Screens

Searching for ScanPoint



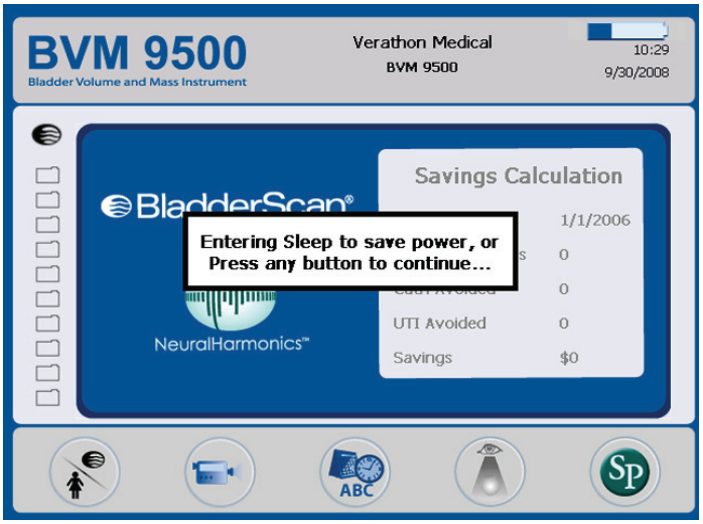
Connected to ScanPoint



Sleep Mode

The Sleep Mode helps preserve battery power. After four minutes of idle time, a Sleep Mode alert message displays for 15 seconds (Figure 29). While the message is displayed, press any button to keep the Console awake and dismiss the message. After 15 seconds, the Console goes to sleep. To wake the instrument from sleep, simply press the Power button.

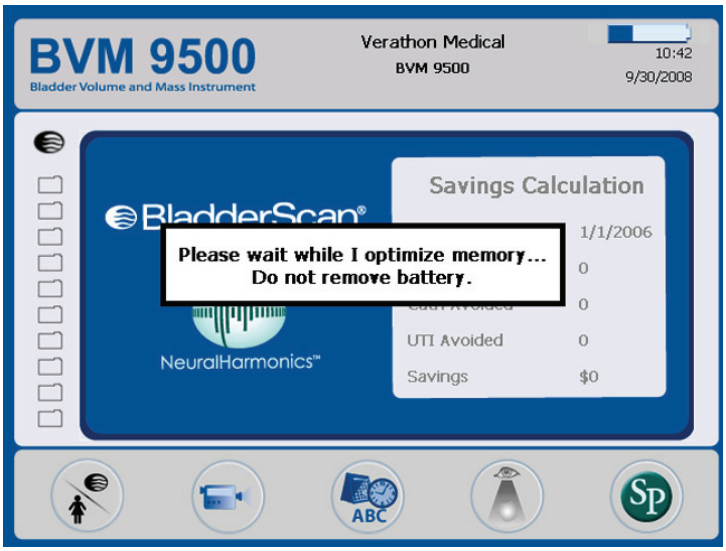
Figure 29. Sleep Mode Screen



Memory Optimization During Power Down

When the power is turned off, the BladderScan BVM 9500 may begin an internal process of memory optimization. This process takes several minutes. When complete, the device will shut down. An alert appears on the display during the memory optimization process (Figure 30).

Figure 30. Memory Optimization Alert



NOTE: DO NOT remove the battery until the device shuts down completely. Replacing the battery while memory is being optimized might disable the instrument as program and exam files might not be rewritten properly.

Measuring Bladder Volume and UEBW

Preparing for the Exam

Before You Begin the Exam:

- Make sure you are familiar with the parts of the BladderScan instrument (see *Introducing the BladderScan BVM 9500* on page 13).
- If you are a new BladderScan instrument user, Verathon® recommends that you perform your first exam on a patient with a moderately full bladder, rather than initially attempting to locate and scan a nearly empty bladder.
- To measure **Ultrasound-Estimated Bladder Weight (UEBW)**, verify that the measured bladder volume is sufficient for a successful exam. The patient's bladder volume must be between **150 ml and 400 ml** to ensure an accurate reading.
- UEBW will be shown as "-- g" when the bladder volume is above or below the recommended range of 150 to 400 ml. UEBW will also be shown this way if the bladder is not centered in the ultrasound cone.
- Check the instrument's battery icon to make sure the battery has sufficient power.

  NOTE: If the battery icon is 1/4 or less full, replace the battery with a freshly charged battery before proceeding. Place the discharged battery in the battery charger to recharge.
- Clean the Probe by wiping it gently with a soft cloth soaked in isopropyl alcohol.

NOTE: When measuring bladder volume and/or UEBW and bladder wall thickness with the BladderScan BVM 9500, it is VERY IMPORTANT to hold the device steady while scanning.

Be aware of the following conditions the patient may have that could affect ultrasound transmission and the accuracy of your exam:

- A catheter in the patient's bladder. The presence of a catheter may affect the accuracy of the bladder volume measurement, but the measurement may still be clinically useful (detecting a blocked catheter, for example).
- Previous suprapubic or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

Do not use the BVM 9500 on:

- Patients with ascites
- Patients with open skin or wounds in the suprapubic region.
- Pregnant patients

Measuring Bladder Volume and UEBW

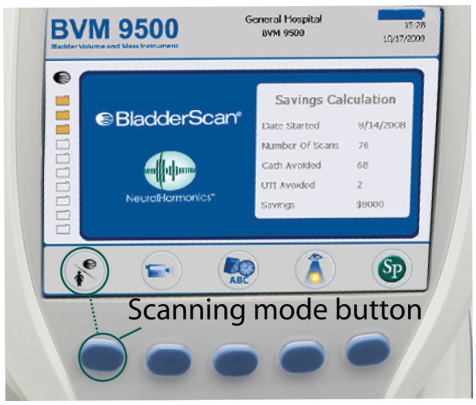
1. **Turn on the BladderScan BVM 9500.**
   Turn on the instrument by pressing the ON/OFF button.

2. **Select the exam mode.**

   Press the MODE button repeatedly to toggle between male and female modes.

   When the female icon is displayed, the BVM 9500 assumes the patient is a female who has not had a hysterectomy.

   Select to measure bladder volume on male patients, or female patients who have had a hysterectomy.

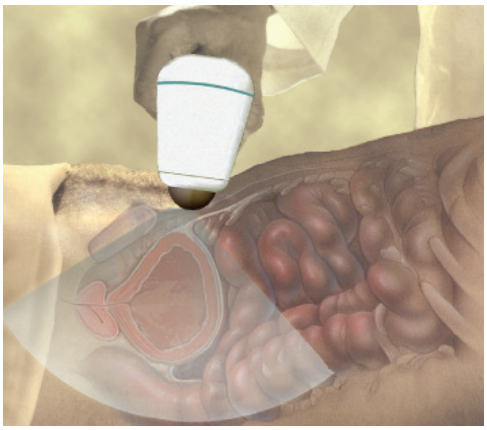


3. **With the patient supine apply gel.**
   Have the patient lie in the supine position with the abdominal muscles relaxed.

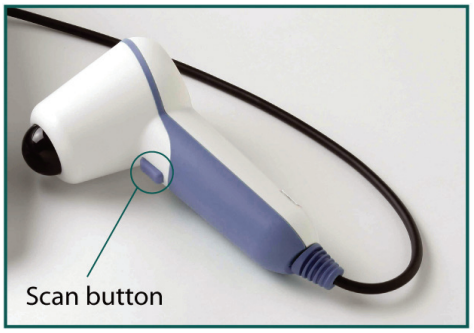
   Palpate the patient's symphysis pubis (pubic bone). Place an ample quantity of gel (with as few air bubbles as possible) midline on the patient's abdomen, approximately one inch (3 cm) above the symphysis pubis (pubic bone).

4. **Aim toward the bladder.**
Standing at the patient's right side, place the Probe on the gel and aim it toward the expected location of the bladder.

   For most patients, this means angling the Probe slightly toward the patient's coccyx (tail bone) so the scan clears the pubic bone.



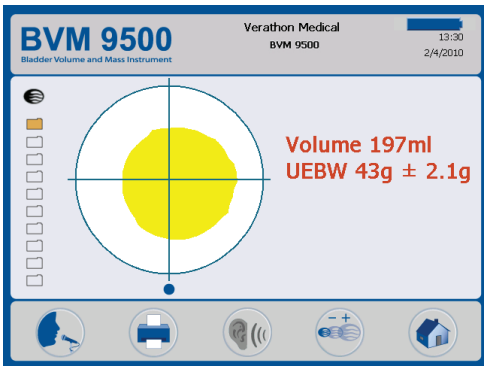
5. **Press and release the SCAN button.**
Press and release the SCAN button, located on the underside of the Probe. As the scan progresses, sections of the bladder will appear on the Console screen. When you hear the end-scan tone, the scan is complete.



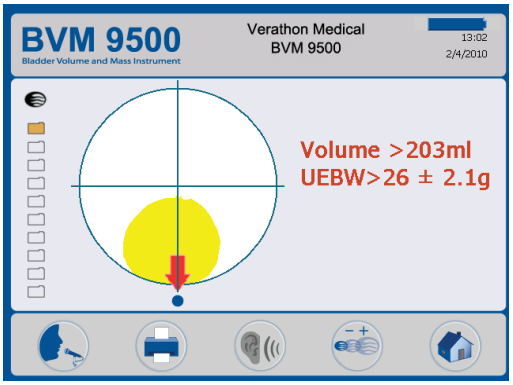
6. **Verify the scan.**
If the scan is "on target" the Probe will display eight arrows. On the Console display, the bladder cavity will be appear in the center of the crosshairs.

   To measure Ultrasound-Estimated Bladder Weight (UEBW), the patient's bladder volume must be between 150 ml and 400 ml to ensure an accurate reading. Bladder volumes above or below this range will return a reading of "--- g" for UEBW.

   A successful scan of bladder volume and UEBW is shown. Note that the bladder volume falls within the desired range of 150-400 ml. The standard deviation value indicating the UEBW measurement confidence is displayed as a +/- range.



6a. Re-aiming



If the scan is significantly “off-target”, the image on the Console screen will show that the bladder is not centered in the crosshairs, and there will be a red arrow pointing in the direction for re-aiming.

The Probe will show an arrow indicating the direction to move the scan head (black tip) of the Probe to be “on target.”

- If the arrow on the Probe is flashing, then you are significantly “off target”.
- If the arrow on the Probe is solid, it means you are slightly “off target”.

To adjust your aim:

- Adjust the angle of the Probe so the scan head moves in the direction of the arrow, or
- Make small movements of the Probe approximately one-half inch (1 cm) in the direction of the arrow until the scan is “on-target”.

The small dot at the base of the crosshairs on the Console screen represents the feet of the patient.

- The top of the crosshairs represents the patient’s head.
- The upper left quadrant represents the patient’s right shoulder.

This orientation should help you in re-aiming the Probe to capture the complete bladder fully in the ultrasound cone.

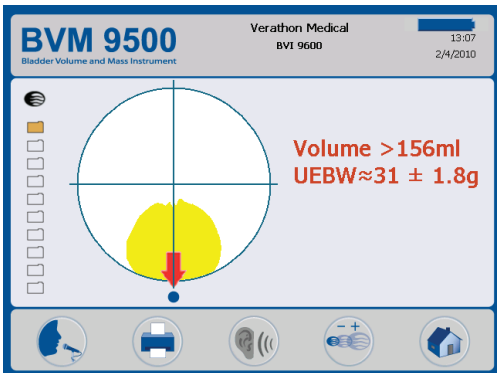
6b. Intepreting Results Screen UEBW Measurement Data

Aiming Arrow Present?	UEBW measurement symbol	Recommended Action
No	=	Accept UEBW measurement
No	≈	Adjust Probe pressure and/or Probe angle and scan again. Depending on patient anatomy, it may not be possible to get an = sign.
No	>	Bladder volume is too large for UEBW measurement
Yes	≈	Move Probe scan head no more than 1/2 inch (1 cm) in direction of arrow; scan again
Yes	>	Move Probe scan head no more than 1/2 inch (1 cm) in direction of arrow; scan again

6c. Volume Outside Scan

In cases where an arrow appears and the UEBW is given as an approximate value, the bladder was not captured within the ultrasound cone.

If this occurs, move the scan head (the black tip) of the Probe in the direction of the arrow on the Probe no more than 1/2 inch and re-scan. Continue adjusting your aim until an accurate scan is achieved.

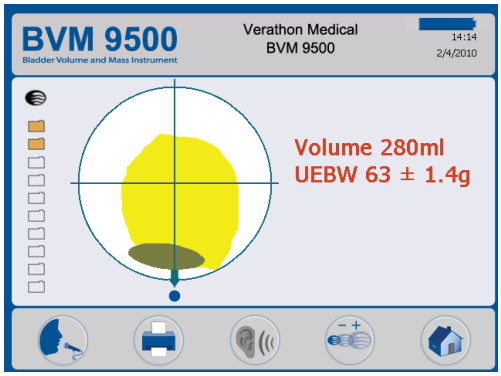


6d. Pubic Bone.

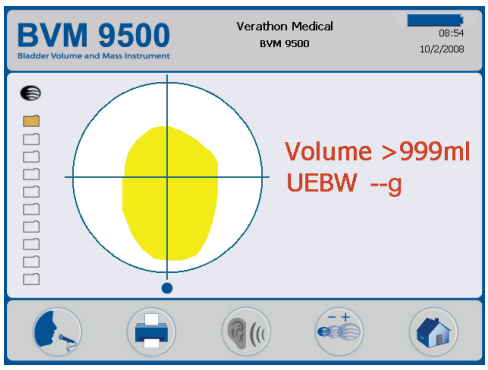
You may also see a display indicating that the pubic bone is inside the ultrasound cone. If this occurs, you should re-aim and re-scan.

Although the bladder may be shown as centered in the ultrasound cone, and your measurement may be complete, there is a possibility that the pubic bone is obscuring part of the bladder.

By re-aiming and re-scanning you can ensure you have captured the bladder fully inside the ultrasound cone.



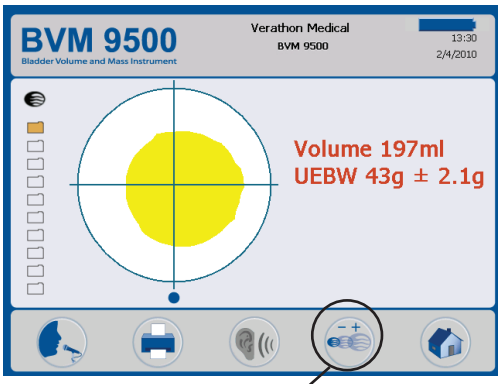
6e. If the bladder volume is greater than 999 ml, the display shows > 999 ml.



7. Manual Measurement of Bladder Wall Thickness (Optional)

To make a manual measurement of Bladder Wall Thickness, please select the MANUAL MEASUREMENT function on the Results screen and follow the process below.

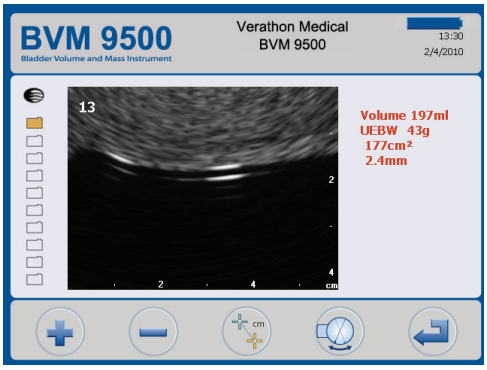
If a manual measurement is not desired, please skip to Step 8.



Manual Measurement

Selecting the MANUAL MEASUREMENT button displays one of two bladder wall images available for manual measurement. The BVM 9500 automatically selects the two best bladder wall images from the 24 scan planes measured.

The Scan Plane Select Icon: allows the user to select between the two best bladder wall images. The number in the upper left corner of the ultrasound image identifies the scan plane.

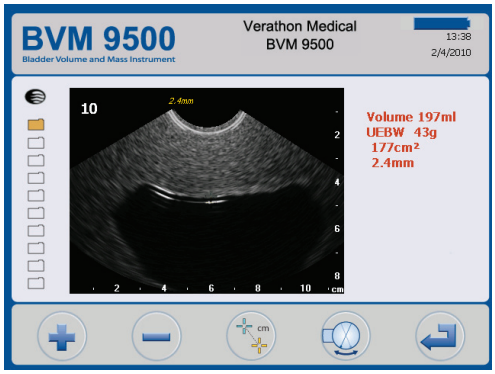


Scan Plane 13 - Bladder Wall Image

Scan planes 10 and 13 are used in this example, but the set of scan plane images will vary with each scan.

Once the user selects the best scan image for making a manual measurement (scan plan 10 is selected in this example), the **+** and **-** buttons allow the user to:

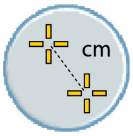
- Widen the image of the bladder wall to a maximum size of 8.5 x 11.5 cm (as shown here)
- Narrow the image to obtain a close-up of the bladder wall with image dimensions of 2.25 x 2.75 cm.



Scan Plane 10 - Bladder Wall Image

Note that Scan Plane 10 – Magnified Image has image dimensions of 4.5 x 5.75 cm, which allows for more accurate placement of the cursors for taking a manual measurement.

To take a manual measurement of bladder wall thickness, please select the CURSOR button.



a. Use the Axis Select icon to select either the “Up-Down” or “Left-Right” axis of movement for the highlighted cursor

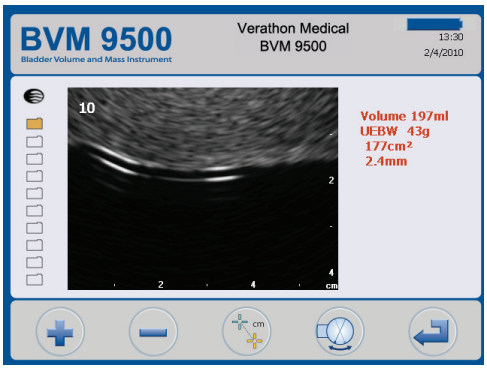
b. Move the highlighted cursor to the edge of the bladder wall.

c. Select the second cursor using the Cursor Select icon.

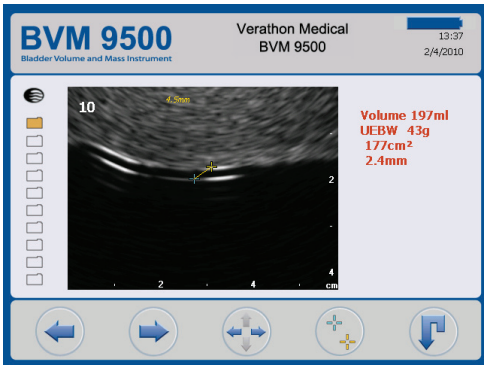
d. Move the second cursor on to the opposite edge of the bladder wall.

e. Press the Return icon to save the measurement and exit Manual Measurement mode.

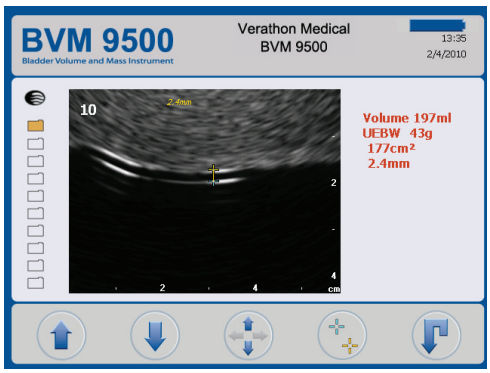
f. Press the Return icon again to return to the Results screen.



Scan Plane 10 - Magnified Image



Scan Plane 10 - Select Second Cursor



Scan Plane 10 - Move Second Cursor

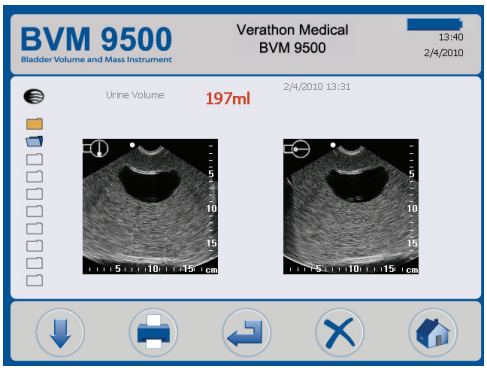
8. **Save, review, and print exam results.**

To save the exam you must voice annotate it.

To annotate, press and release the RECORD button on the Console. When you see the RECORD button icon change to a STOP button icon, record the patient information by speaking into the Probe microphone. When the hourglass icon disappears, press the LISTEN button to replay the annotation.

To print exam results via the onboard printer, press the PRINT button.

To review previous scan images, press the REVIEW button. (You must first save the exam before you can review it.) On the review screen, the user can review all currently saved exams and can print, replay voice annotations, or delete exams.



Review Screen 1 - Bladder Volume

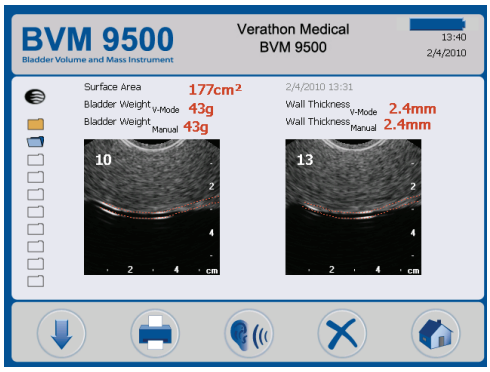
The Review Screen consists of two screens:

Review Screen 1 shows the bladder volume measurements. Pressing the RETURN button displays **Review Screen 2**, which will display:

- Bladder Surface Area
- Ultrasound Estimated Bladder Weight (V-Mode)
- Ultrasound Estimated Bladder Wall Thickness (V-Mode)

If manual measurements were taken, then two additional measurements will be displayed:

- Bladder Weight (Manual)
- Wall Thickness (Manual)



Review Screen 2 - UEBW and Manual Measurements

To perform another exam, press the HOME button.

9. **Finish the exam.**

Once you have completed the scan, wipe the ultrasound gel off the patient and the Probe. For ScanPoint® subscribers, logging onto ScanPoint automatically transfers and saves your annotated exams to your Windows® computer.

Additional Scanning Tips

NOTE: When measuring bladder volume and/or UEBW and bladder wall thickness with the BladderScan BVM 9500, it is VERY IMPORTANT to hold the device steady while scanning. Avoid changing position, angle or pressure.

Applying too much pressure when scanning may lead to a Greater Than (>) symbol preceding the measurement on the screen. If this happens, apply less pressure and re-scan.

Volume reading will be affected by:

- The presence of scar tissue
- The presence of a catheter
- Overly obese patients -- with obese patients, lift as much abdominal adipose tissue out of the way of the instrument as possible. You can also apply more pressure to the Probe to reduce the amount of adipose tissue through which the ultrasound must pass.

To ensure accurate results, make sure that:

- You use sufficient gel and make sure there are no air gaps between the Probe and the patient's skin.
- You are holding the instrument steady while scanning (avoid changing its position, angle, or pressure).
- You are using enough pressure to maintain good skin contact until the scan is complete.
- There is not a catheter in the patient's bladder. The presence of a catheter may affect the accuracy of the bladder volume measurement, but the measurement may still be clinically useful (detecting a blocked catheter, for example).

NOTE: The BVM 9500 is able to scan rapidly and repeatedly throughout the day. If however scans are taken quickly, in rapid succession, over a 30 minute period, some slowing in performance may be noticed. While this may occur rarely, it is normal for the instrument.

Recording a Voice Annotation

After performing an exam, you can record additional information about a patient to be stored with the exam results.

The instrument can store ten scans with voice annotations, so you can perform multiple exams on your rounds. If you are using the optional ScanPoint® with QuickPrint software, you can upload saved exams to your PC. (Refer to the ScanPoint with QuickPrint User's Manual for more information.)

To record a voice annotation:

1. Press the RECORD button. Recording begins and the RECORD button becomes a STOP button.
2. The microphone is located just above the aiming display on the Probe. Hold the microphone approximately 6 inches (15 cm) from your mouth when you are recording the annotation and speak clearly.

   Be sure to include all relevant exam information, including the patient's ID and the name of the person performing the exam.

3. When you have finished your annotation, press the STOP button. An hourglass icon will be displayed while your annotation and exam are updated and stored. After the annotation has been saved, to listen to your annotation, press the LISTEN button.

   If you are not satisfied with the recording, press RECORD again to record a new annotation.

IMPORTANT!

- If you do not record a voice annotation for a particular exam, that exam will be lost and the next exam you perform will overwrite the non-annotated one.
- If the instrument battery runs low or the instrument goes into sleep mode, any non-annotated exam data is lost. However, the instrument does not erase any annotated exam results when it goes into sleep mode. To make sure you do not lose any patient data, it is a good idea to add a voice annotation to every patient exam.
- You can make a new recording only if the instrument still displays the bladder volume for that particular exam.

4. When you are satisfied with your recording, press the HOME button to perform another measurement.
5. If you are using the BVM 9500 in conjunction with ScanPoint® software, you can view exam results and annotations on your PC. Please refer to the ScanPoint User's Manual for more information.

Deleting a Saved Exam

Saved exams are indicated by yellow folder icons along the left edge of the display. To delete a saved exam:

1. Open the Review Screen. (From the Home Screen press .)
2. Press the button until the desired exam is highlighted (blue).
3. Press the button to delete the exam.

Printing

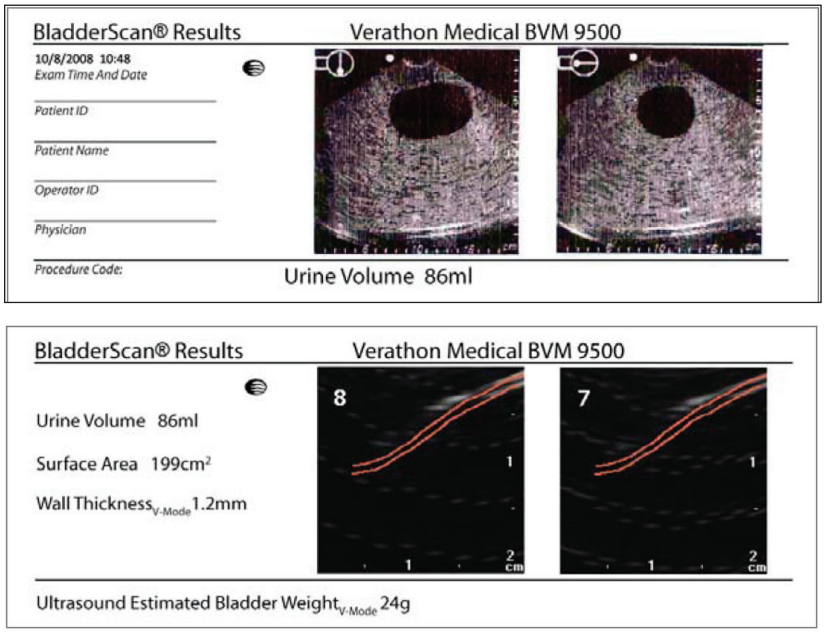
You can use the BladderScan BVM 9500 onboard printer to print the ultrasound images captured during the scan (Figure 31 is an example).

To print exam results, you must first record a voice annotation as described previously. When this is complete, press the PRINT button.

Adding Additional Information

The label provides fields for Patient ID, Patient Name, Operator, and Physician. This information must be entered manually.

Figure 31. Exam Results Printout Using the Onboard Printer



NOTE: If the facility name, date, and time have not been set, those lines will be skipped on the printout. The BVM 9500 prints on thermal paper, which fades over time.

For maximum storage life, Verathon® recommends that you photocopy the printout.

Histogram of Cost Savings

Each volume measurement from a completed scanning procedure is stored in the memory of the BladderScan BVM 9500 in one of eleven volume ranges (each with a 100 ml increment). This data is analyzed and can be displayed on the BVM 9500 at any time. The cost savings screen lists: Date Started, Number of Scans, Cath Avoided, UTI Avoided, Savings.

Cost Savings Criteria

Cost savings are based on the following criteria:

- **Catheterizations avoided:** Urinary catheterization may be unnecessary. Thus, by using the BVM 9500, these catheterizations are avoided. The default setting (for volume below which catheterization is unnecessary) is 200 ml.
- **UTIs avoided:** Studies indicate that a certain percentage of unnecessary catheterizations lead to urinary tract infections (UTIs).

  By avoiding unnecessary catheterizations, the resulting UTIs are thereby avoided. The default setting (for percent of catheterizations leading to UTIs) is 3%.
- **Associated UTI costs:** Literature suggests that the additional costs associated with treating UTIs amounts to $1875.00 per patient infection. The default setting is $1870.00.
- **Cost of catheter kits:** The default setting is $3.00 per kit.
- **Total Cost Savings from Using the BVM 9500 =**
  (Catheterizations avoided x catheter costs) + (UTIs avoided x UTI costs)

NOTE: The default settings can be changed to reflect the rates and costs at your facility by selecting from the Home screen: (SETTINGS) > SAVINGS PREFERENCES**.** See page 42, *Savings Preferences Screen* for more information on customizing Savings Preferences.

Cleaning and Maintenance

Cleaning the BladderScan BVM 9500

1. Use a soft cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent) to wipe the Probe until it is thoroughly cleaned.
2. If you use a detergent solution to clean the instrument, remove all residual detergent. Dry the instrument with a clean, soft cloth.
3. Alternatively, dampen a soft cloth in any glutaraldehyde-based hospital disinfectant solution such as Cidex® or Cidex 7® from Advanced Sterilization Products, or Sporocidin® from Sporocidin International. Wipe the instrument with the dampened cloth.
4. To remove all traces of disinfectant solution, wipe the instrument with a clean soft cloth dampened in sterile water or cleaning solution. Verathon® recommends wiping the device three separate times to remove all residual disinfectant.
5. Thoroughly dry the instrument with a clean, soft cloth before using.

IMPORTANT! Failure to heed the following warnings may cause device damage not covered by the BladderScan BVM 9500 warranty.

- Do not immerse the instrument in disinfectant solution.
- Do not use CidexPlus® to disinfect the instrument. CidexPlus® will damage the plastic enclosure.
- Do not subject any part of the instrument to steam sterilization or ethylene oxide sterilization.

NOTE: "Ultrasound probes that are non-critical devices only need to be cleaned and low level disinfected between patient uses." **Guidance for Industry and FDA Staff -- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers -- Appendix D: Cleaning, Disinfection and Sterilization.** Accessed at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm098001.htm

Regular Inspections and Maintenance

Verathon Medical recommends that the BVM 9500 be certified by an authorized BladderScan Service Center once a year. Certification service includes comprehensive inspection and testing of the instrument to ensure accurate performance in clinical use. For more information, please contact your authorized BladderScan Service Center, your local BladderScan distributor, or Verathon Medical Customer Care Department at 1.800.331.2313 (North America only). International customers, please refer to the contact information on page 66.

NOTE: ScanPoint® Online customers can maintain device certification via the Internet by accessing their ScanPoint account. For more information about using ScanPoint Online, please refer to the ScanPoint User's Manual.

Weekly Inspections

Once a week, you should inspect the Probe and cable for physical faults or cracks. Cracks that allow the ingress of fluid may affect the performance of the instrument. Any apparent cracks or faults in the Console, Probe, or the cable that links the Console and the Probe, must be referred to your authorized BladderScan Service Center, your local BladderScan distributor, your local Verathon Medical representative, or the Verathon Medical Customer Care Department.

IMPORTANT! If you see any physical faults or cracks in the instrument, discontinue use immediately and contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

Using the Built-in Self-Test Utility

The BVM 9500 can perform a number of self-diagnostic tests. To access the Self-Test utility:

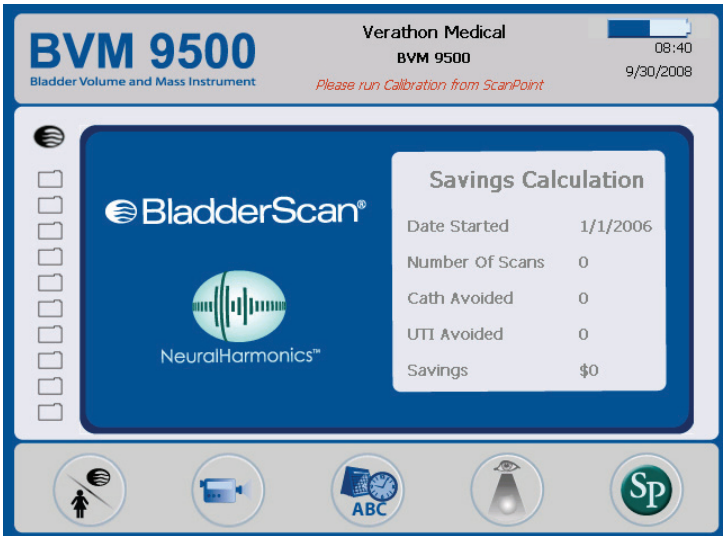
1. From the Home screen, press the SETTINGS button:
2. When the Settings screen opens, press the or buttons until SELF-TEST is highlighted (red), then press to open the Self-Test screen.
3. When the Self-Test screen opens, testing begins automatically with the display providing status and results.
4. When test is complete, press the SETTINGS button to return to the Settings screen, then press the HOME button to return to the Home screen.
5. If any test results were failed or abnormal, contact your authorized BladderScan representative, or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

Calibrating the BladderScan BVM 9500 Using ScanPoint

The BladderScan BVM 9500 must be periodically calibrated to ensure that the instrument is providing the most accurate results. Calibrating ensures accurate and proper alignment of the instrument's internal coordinate system. If you do not perform the calibration by the prescribed date, the instrument can still be used to take scans but measurements may be compromised.

When calibration is due, a warning appears in the display header (Figure 32).

Figure 32. Calibration Warning



If you do not have ScanPoint® with QuickPrint, you must send your instrument in to an authorized Verathon service center for calibration. Contact your Verathon Medical Customer Care Center for more information. For contact information, please see Contacting Verathon® on page 66.

Self-Calibration

Self-calibration requires the ScanPoint with QuickPrint System and a Calibration Kit (P/N 0620-0340). For instructions on software requirements and installation, please refer to the ScanPoint User's Manual.

The entire calibration process takes approximately 15 minutes. ScanPoint® plans allow for calibration of the instrument as often as you like. You do not need to wait until the next scheduled calibration date. However, at a minimum, you must calibrate the instrument once every 12 months

Device Repair

The BladderScan BVM 9500 Console, Probe, and battery charger/wireless hub are completely sealed. There are no user-serviceable components. Verathon does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories.

Premium Warranty customers have access to a loaner unit and free shipping options which vary according to plan.

If you have any questions, contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

Unit Disposal

The BladderScan BVM 9500 and related devices may contain lead, mineral oils, batteries, and other environmentally hazardous materials. When the BladderScan BVM 9500 has reached the end of its useful service life, return the device, battery charger/ wireless hub, and related accessories to a Verathon Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

Troubleshooting

Help Resources

Verathon® provides an extensive array of customer service resources, described in the table below.

You can obtain copies of this manual, Quick Reference Cards, and clinical studies by visiting the Verathon Web site at **http://www.verathon.com** or by contacting your Verathon Medical representative. For contact information, please see page 66.

Resource	Description
BladderScan BVM 9500 In-Service CD	CD included with the BVM 9500 that provides information on how to use the instrument. Includes user manual, quick reference cards and training videos.
Training modules	Training modules explaining how to take bladder volume and UEBW measurements can be found on the In-Service CD. The tutorials are also installed on the instrument and can be accessed by pressing the button from the Home Screen.
BladderScan BVM 9500 Quick Reference Cards	Summary of procedures for using the BladderScan system.
Clinical Studies	Scientific papers on BladderScan use.
ScanPoint® Online	ScanPoint Online provides customers: ◆ The ability to calibrate and certify devices online anytime you wish. ◆ Automatic data backup and archiving (HIPAA compliant). ◆ Automatic software upgrades. ◆ Access to real-time troubleshooting from Verathon®.
Premium Warranty	A Verathon device warranty plan that provides all the benefits of ScanPoint Online (preceding paragraph) and also: ◆ All repairs performed free of charge. ◆ Instrument insurance: A perpetual warranty against outdated technology with free upgrade / replacement when your device is no longer manufactured. ◆ Free loaner program. ◆ Free shipping.

Resource	Description
Verathon® Web site	http://www.verathon.com includes many in-service training resources. From the Verathon Home page, select “BladderScan®.” On the BladderScan® page, select “Customer Service.”
Phone support	In North America, call: 1.800.331.2313. International customers, please refer to contact information on page 66.

Icons on the BladderScan® Console

The following icons may appear on the instrument’s LCD screen.

Symbol	Meaning
	(Solid arrow) The bladder is contained within the image cone (cone-shaped area in which the Probe transmits ultrasound waves), but not centered. You may be able to obtain a more accurate measurement by re-aiming the Probe in the direction indicated by the arrow.
	Battery power level: ◆ Indicates a fully charged battery. ◆ Indicates a battery 50% to 75% charged. ◆ Indicates a battery 25% to 50% charged. ◆ Indicates a battery that is nearly discharged and can power only a few more scans. ◆ Indicates the battery must be changed.
	The patient is a female patient who has not had a hysterectomy.
	The patient is male, or a female who has had a hysterectomy.
>	The bladder is too large to be contained within the scan cone, or the bladder contains more than 999 ml of urine.

Diagnosing Problems

Instrument Does Not Turn On

If the instrument does not turn on, this is usually due to a dead or discharged battery and can be remedied by replacing the dead battery with a charged battery. Check the battery icon in the upper right corner of the LCD display. If the battery icon does not display any power segments, replace the battery.

When the battery charge is too low to allow normal operation (but not too low to permit operation of the internal circuitry) the device displays the following message:

BATTERY CHARGE LEVEL IS TOO LOW FOR
INSTRUMENT OPERATION. RECHARGE BEFORE NEXT USE.

In this case, the battery must be recharged or replaced with a charged one.

UEBW displayed as “-- g”

To measure Ultrasound-Estimated Bladder Weight (UEBW), the patient’s bladder volume must be between 150-400 ml to ensure an accurate reading. Above or below this range, UEBW is shown as “-- g”.

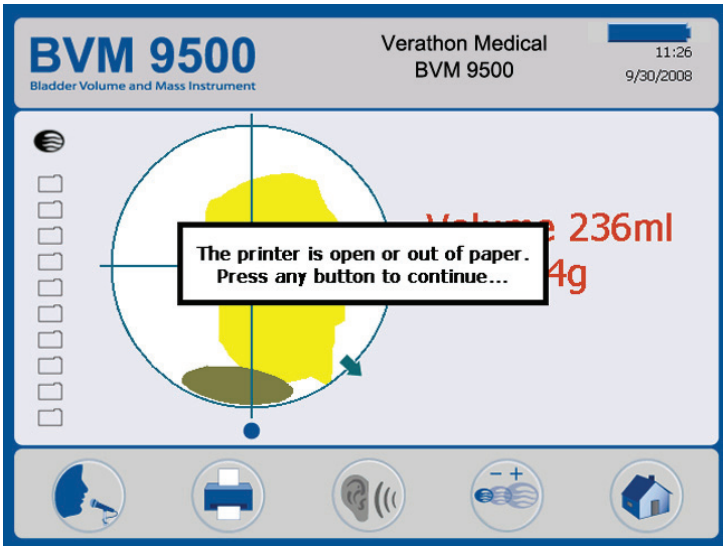
UEBW may also show as “-- g “ when the bladder is not centered in the ultrasound cone.

Printer Problems

No Paper

The BladderScan BVM 9500 senses the presence of paper and automatically displays this image when the printer is out of paper (Figure 33).

Figure 33. Printer Out of Paper Screen



For instructions on loading paper, please refer to the section in this manual titled *Load a Roll of Thermal Paper* beginning on page 22.

Too Hot

The BVM 9500 displays the message “Too hot” if the print head overheats. In this case, turn off the BVM 9500 immediately. This condition may be the result of a paper jam. To clear the paper jam see the following paragraph.

Clearing a Paper Jam

If the paper will not advance through the printer, open the printer door on the back of the Console and clear the paper jam.

Warranty

Verathon® Inc. warrants the BladderScan BVM 9500 against defects in material and workmanship as long as it is covered by the Premium Warranty.

Pursuant to this warranty, a service center authorized by Verathon will repair or replace units that prove to be defective during the warranty period.

This warranty does not apply if the unit was misused or modified by anyone other than a service center authorized by Verathon.

The unit must be used in accordance with the instructions contained in this manual. Consumable items are not covered in this warranty and should be used in conformance with Verathon product specifications.

For further details, consult your Premium Warranty. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for warranty terms.

Disclaimer of Additional Warranties

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding Warranty section. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. This information, descriptions, recommendations, and safety notations in this manual are based upon Verathon experience and judgment with BladderScan instruments as of September 2010. The contents of this manual should not be considered to be all-inclusive, or to cover all contingencies.

The physician who directs the use of the BladderScan BVM 9500 at the institution where it is in use is responsible for keeping current with clinical research in bladder volume measurements.

Please direct any questions or problems concerning bladder volume measurement, using the instrument, or the interpretation of data to the responsible physician.

Contacting Verathon®

The team at Verathon is committed to modernizing healthcare delivery by putting patients first. Our products support healthcare professionals by providing accuracy, utility, and excellence. For additional product and company information, visit the Verathon Web site at **http://www.verathon.com**. If you have any questions or comments about Verathon products and services, please contact us at:

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For contact information for Verathon subsidiaries, please visit our web site at **www.verathon.com/ContactUs.htm**.

Safety and Performance Summary

- The BladderScan BVM 9500 computes the volume of the urinary bladder based upon twenty-four cross-sectional ultrasound images.
- To achieve accurate measurements, have the patient rest quietly in a supine position.
- Errors in usage tend to result in the underestimation of bladder volume, except in cases where the Probe is moved during scanning. In this case, the measurement may overestimate the patient's bladder volume.
- We recommend that new users use the BladderScan BVM 9500 to measure patients with moderately full bladders rather than initially attempting to locate a bladder with a low urinary volume.
- To conserve battery power, the BladderScan BVM 9500 powers down automatically when not in use (goes into "sleep mode").

WARNING! Risk of explosion.
There is a possible risk of explosion if the BladderScan BVM 9500 is used in the presence of flammable anesthetics.

WARNING! Risk of patient injury.
Do not use the BladderScan BVM 9500 on patients with open skin or wounds in the suprapubic region.

CAUTION! Risk of inaccurate measurements.

- Accuracy is compromised if the user does not obtain an optimal, repeatable image.
- The BladderScan BVM 9500 is not intended for use on pregnant patients.
- The patient being scanned should not have a catheter in his/her bladder. This could create microbubbles in the bladder, which will compromise the accuracy of the measurement.
- Use care when scanning suprapubic and pelvic surgery patients. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

CAUTION! Risk of Fire and Burns. Do not disassemble, heat above 60° C (140° F), or incinerate battery. Keep battery out of reach of children and in original package until ready to use. Dispose of used batteries promptly according to local recycling or waste regulations.

Parts and Accessories

BladderScan BVM 9500 System Components

The following components are included with your BladderScan BVM 9500 system.

Part Number	Description
0570-0208	BVM 9500 Probe
0570-0207	BVM 9500 Console
0570-0193	Battery Charger/Wireless Hub
0400-0067	Desktop Power Supply
0400-0066	Rechargeable batteries (2 included)
0800-0319	Roll of Thermal Paper: Properly-sized paper for the on board printer.
0620-0340	Calibration Kit (Optional - requires ScanPoint® with QuickPrint software)
0800-0347	BladderScan BVM 9500 Medical Cart (optional)
0900-1596	BladderScan BVM 9500 User's Manual (on In-Service CD)
0900-2103	BladderScan BVM 9500 In-Service CD (with User's Manuals, Video Tutorials, and Quick Reference Cards)
0900-1601	ScanPoint User's Manual (on In-Service CD)
0900-2102	Quick Reference Card - BladderScan BVM 9500 Bladder Volume and UEBW Measurement
0900-1447	Quick Reference Card - Calibration
0810-0201	Universal Accessory Basket for Medical Cart (optional)

To order any of the above parts, contact your authorized Verathon Medical sales representative or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

Product Specifications

Symbol Directory

The following table explains the industry symbols used to indicate the BladderScan system compliance with international and national standards and regulations.

Symbol	Meaning
	Marked in accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (solid bar indicates product was put on the market after 13 August 2005.)
	Class II equipment protected throughout by double or reinforced insulation.
	Type BF applied part with EN/IEC-60601-1.
CE 0123	CE marked in accordance with the Medical Device Directive (MDD).
C SA US	Canadian Standards Association (CSA) mark of certification to United States standards for electromedical equipment.
0400-0066	This unit is powered by a Lithium-Ion battery pack. The Verathon® part number for the battery pack is 0400-0066.

Standards and Regulations Compliance

Verathon certifies that all units are in compliance with all applicable international and national standards and regulations, including but not limited to the following:

Specification	Standard
International Electrotechnical Commission	EN/IEC 60601-1 Amendments 1 and 2 and EN/IEC 60601-1-2 (EMC)
Safety Standard	EN/IEC 60601-2
Medical Device Directive	MDD 93/42/EEC Annex 1
Canadian Standards Association	C22.2 No. 601.1-M90 (Master Contract No. 177198)
Underwriters Laboratories, Inc.	UL 60601-1
Health Insurance Portability and Accountability Act (HIPAA)*	

*For details on Verathon compliance with privacy rules, please refer to the information in the QuickPrint Help menu (select PRIVACY AGREEMENT).

Electromagnetic Effects

There are no restrictions on the use of BladderScan BVM 9500 due to its electromagnetic characteristics. Both the emissions from the BladderScan BVM 9500 and the susceptibility of this instrument to interference from other sources are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure that was used is specified in EN/ IEC55011: 1991 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

BladderScan BVM 9500 is suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a health care professional. An indication of adverse electromagnetic effects from BladderScan BVM 9500 on another electronic device would be a degradation of performance in the other device when the devices are operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Verathon.

BladderScan BVM 9500 will operate normally in the proximity of other potential interference sources, and has demonstrated immunity at a field strength of 3 V/m (per EN/IEC 60601-1-2, 36.202.2.1). You do not need to take any other precautions regarding exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure, or variations in pressure, acceleration, or thermal ignition sources.

BladderScan BVM 9500 Instrument Specifications

For technical performance assessment in an acoustic laboratory, the Probe cannot be immersed in water.

Item	Specification
Input	Lithium Ion Battery Pack. Verathon P/N 0400-0066.
Output	No load to full load at rated voltage. Refer to unit label.
Insulation	The power supply is Class I with basic insulation to each terminal.
Transient Overvoltage:	Category II
Weight	5.2 lb (2.36 kg) (with battery)
Display	13.36cm W x 10.13cm H (5.26” W x 3.99” H) (640 x 480 pixels, 120 dpi)
Integrated Printer	Thermal label printer
Languages	English (default), Chinese Simplified, Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Portuguese, Spanish, Swedish, Turkish

Ultrasound Output Parameters - Acoustic Output Limits

Item	Specification
Maximum ultrasound I_{sptad} (Intensity Spatial Peak Temporal Average derated)	≤ 5.0 mW/cm^2
I_{sppad} (Intensity Spatial Peak Pulse Average derated) Range	≤ 60.0 W/cm^2
Maximum MI (Mechanical Index)	0.95 max
TIS/TIB/TIC Range	0.0 - 4.0
Transducer diameter	13 mm (0.512 inches)
Transducer resonant frequency	1.74 MHz, 3.0 MHz and 7.37 MHz
Transducer bandwidth	80% at 10 dB
Time from 3D scan initiation to result display	< 10 seconds

Accuracy Specifications

The accuracy specifications assume the instrument is being used according to the instructions provided by Verathon, scanning a tissue-equivalent phantom.

Specification	Description
Bladder volume accuracy	± 15%, ± 15 ml (on a Verathon tissue-equivalent phantom)
Bladder volume range	0 - 999 ml
UEBW accuracy	± 10%, ± 3 g (on a Verathon tissue-equivalent phantom)
UEBW range	20 - 100 g
Wall thickness accuracy	± 10%, ± 1 mm (on a Verathon tissue-equivalent phantom)

BladderScan BVM 9500 Operating Conditions

The BladderScan BVM 9500 is designed to function properly within the following specifications:

Condition	Description
Use	Indoor
Ambient temperature range	+10 - +40º Celsius (+50 - +104º Fahrenheit)
Atmospheric pressure range	700 hPa - 1060 hPa
Relative humidity	30% - 75% non-condensing
Water resistance	Rated at IPX1 (indicates DRIP-PROOF, a higher than ORDINARY level of protection from drips, leaks, and spills)

BladderScan BVM 9500 Storage Conditions

The BladderScan BVM 9500 is designed for storage under the following conditions:

Condition	Description
Storage	Indoor
Ambient temperature range	-20 - +60º Celsius (-4 - +140º Fahrenheit)
Atmospheric pressure range	500 hPa - 1060 hPa
Relative humidity	20% - 95% non-condensing

BladderScan BVM 9500 Displays, Controls, and Indicators

The BladderScan BVM 9500 provides the following controls, connectors, and features:

Instrument Buttons

POWER ON/OFF, BRIGHTNESS (▲/▼), and VOLUME (▲/▼) are located on the lower half of the Console. SCAN (on the Probe). The five buttons below the Console LCD have variable functions depending on current instrument mode as follows:

Screen/Mode	Active Buttons
Start up screen Appears when the instrument is first turned on.	POWER, VOLUME, BRIGHTNESS (1) - (5) No function.
Home Screen Appears when the instrument is turned on.	POWER, SCAN: opens Aim/Scan screen, (1) PATIENT TYPE: toggle between two bladder volume modes: female with uterus, all other patients, (2) TUTORIAL: opens Tutorial screen, (3) SETTINGS: opens Settings screen (4) REVIEW: opens the Review screen, (5) SCANPOINT®: transmits saved exams to ScanPoint®.
Scan Screen: Appears when the operator presses and releases the SCAN button.	POWER: No function SCAN: Press to take a scan. Buttons (1) - (5): No action.
Results Screen Appears when the operator releases the SCAN button (after aiming).	POWER, SCAN: opens Aim/Scan screen: (1) RECORD: press to record voice annotation, press STOP to end voice annotation, (2) PRINT: print to onboard printer, (3) PLAY: press to play voice annotation; otherwise, no function, (4) ZOOM: Image Zoom screen for manual measurement of bladder wall thickness. (5) HOME: return to Home screen.
Review Screen Review, replay, print, or delete saved exams	POWER, SCAN, (1) NEXT: select next exam in memory, (2) PRINT: print to on-board printer, (3) RETURN/PLAY: On first Review screen, switches to second screen for additional data (UEBW, Bladder Wall Thickness); On second Review screen, plays voice annotation for currently selected exam, (4) DELETE: delete currently selected exam, (5) HOME: return to Home screen.
Tutorial Screen View the menu of training modules.	POWER, (1) Skip to next tutorial, (2) Skip to previous tutorial, (3) Select tutorial for viewing (4) No function, (5) Home (return to Home screen).
Video Viewing Screen The video viewing screen.	POWER, (1) No function, (2) Play/Pause, (3) Return to Tutorial (4) No function, (5) Home (return to Home screen).
Settings Screen Edit clinic name, date & time, general preferences, savings preferences, and self-test options.	POWER, (1) Select next setting in list, (2) Select previous setting in list, (3) Enter (proceed to the selected screen), (4) No action, (5) Home (return to Home screen).

Screen/Mode	Active Buttons
Alpha-Numeric Screen Displays alpha-numeric characters for entering information.	POWER, (1) Move down, (2) Move right, (3) Add currently selected character, (4) Delete currently selected character, (5) Return to main setup screen.
Date & Time Screen Allows the user to set the date and time	POWER, (1) Move forward to next changeable unit, (2) Move back to previous changeable unit, (3) Add/ toggle units as appropriate (hold down to move faster), (4) Decrease/toggle units as appropriate (hold down to move faster), (5) Save current date/time entries and return to main setup screen.
General Preferences Screen Set preferences for language, time and date format, time zone, UTI rate and cost, and currency	POWER, (1) Select next setting in list, (2) Select previous setting in list, (3) Select next option/Enter, (4) Select previous option, (5) Home (return to Home screen). Preferences list and options: Languages: English (default), Chinese Simplified, Chinese Traditional, Czech, Danish, Dutch, Finnish, French, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Portuguese, Spanish, Swedish, Turkish. Date format: mm/dd/yyyy, dd.mm.yyyy, yyyy-mm-dd Time Format: 12-hour, 24-hour Calibration Warning: On (default), Off. When “On” is selected, a calibration warning will appear in the display header when the device is due for calibration. Print Report Type: B-Mode (default), C-Mode Print UEBW: On (default). Off
Saving Preferences Screen	UTI Rate: 1 % - 100 % in increments of 1% UTI Cost: $10 - $100,000 in increments of $1 Catheter Cost: $1 to $1000 in increments of $1 Catheter Volume: 20 ml - 100 ml in increments of 20 ml Currency: $ / € / £ / ¥ Savings Calculation: Since new, Since 1/1/2006, Reset Now, Print Since New, Print Recent, Hide Savings.
Self-Test Screen	(1) to (4): No function; (5) Return to Settings screen
ScanPoint® Screen	(**NOTE:** Only available when used with ScanPoint with QuickPrint software.) POWER, (1) No function, (2) No function, (3) No function, (4) CANCEL, (5) No function.

Instrument Display

The instrument display is divided into three horizontal panes:

- The header pane displays the instrument mode (Male or Female mode), the institution name, date, time and a battery status icon.
- The center pane is the main display area. The information displayed in the center pane varies depending on the device mode.
- The footer pane displays icons that indicate button functions, as described in the preceding table.

Screen/Mode	Display
Home Screen	Mode indicator, Memory indicator, Savings Calculation table.
Scan Screen	Appears when the operator presses the SCAN button. As bladder volume is calculated, the display refreshes and updates until the scan is complete.
Results Screen	Appears when a bladder volume scan is complete. Displays calculated bladder volume, UEBW, patient type, available memory and Aiming display.
Review Screen	Displays either the Aiming display or the Image display along with calculated bladder volume.
Tutorial Screen	Lists available video tutorials.
Settings Screen	Lists options for setting name, date and time, general and savings preferences, and self text.
Name Screen	A grid of alpha-numeric characters.
Date & Time Screen	Options for setting date, time and display formats.
Preferences Screen	List of available settings and their current values.
Self-Test Screen	Displays test progress and results.
ScanPoint® Screen	When ScanPoint with QuickPrint is installed: Displays status information about the ScanPoint communication.

Battery Charger/Wireless Hub Specifications

The battery charger/wireless hub is powered from a standard wall outlet (adaptable to international power standards). The battery charger/wireless hub can charge two batteries simultaneously.

Operating Conditions

The following are proper operating conditions for the battery charger/wireless hub:

Specification	Description
Use	Indoor
Ambient temperature range	+41 - +104º F (+5 - +40º C)
Atmospheric pressure range	70 kPa - 106 kPa
Relative humidity	30 % - 75 % non-condensing
Water resistance	Rated at IPX 0 (ordinary equipment without protection against ingress of water)
Computer connection	USB 2.0
Charger	Powered by a desktop DC power supply.
Input voltage	100 - 240 VAC RMS
Input frequency	50 - 60 Hz
Input current	1 Amp max
Input connection	2 wire IEC 60320 C7
Output	9v at 1 Amp
Insulation	Class II with double insulation
Fuses	250 VAC, 2A, quick acting
Testing	CSA 60950-1-03/UL 60950-1

Storage Conditions

Condition	Description
Use	Indoor
Ambient Temperature Range	+41 - +104º F (+5 - +40º C)
Atmospheric pressure range	70 kPa - 106 kPa
Relative humidity	30% - 75% non-condensing
Water resistance	Rated at IPX 0 (ordinary equipment without protection against ingress of water)

Battery Specifications

The BladderScan BVM 9500 is provided with two Lithium Ion batteries. A battery icon on the instrument display is always present indicating how much power remains and when the battery needs to be changed. The user can change the battery whenever necessary. Removing a discharged battery and replacing with a fresh battery will not erase any saved exams or user settings. Use only the battery charger provided with the BVM 9500. Any other battery charger may damage the battery pack.

The batteries meet the following specifications:

Condition	Description
Battery type	Lithium Ion
Battery life	A fully charged battery can provide approximately 30 exams within a 24-hour period.
Charging time	Charging time offline will take no more than six hours from an empty battery to a full charge.
Rated capacity	4800 mAh
Normal voltage	11.1 V
Max charging voltage	12.6 V
Max weight	350 g
Width	3.11 in (79 mm)
Length	4.65 in (118 mm)
Thickness	0.91 in (23 mm)

Glossary

Term	Meaning
Aiming display	Ultrasound image showing the bladder on a white field with blue crosshairs, the Aiming Display shows the location of the bladder within the ultrasound cone radiating from the Probe. Also referred to as C-Mode
B-Mode	Ultrasound images showing an abdominal cross-section with the bladder shown as a dark circle. Also referred to as the Results display.
Battery Charger/ Wireless Hub	The unit that charges the Lithium Ion batteries that power the BladderScan BVM 9500 and simultaneously receives and sends information from/to a BVM 9500 instrument within communication range.
BladderScan	The BladderScan instrument transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume and UEBW.
C-Mode	Ultrasound image showing the bladder found within the ultrasound cone. Also referred to as the Aiming display.
Calibration	Checking the accuracy and function of your BladderScan instrument by comparing it with a known standard.
Calibration Kit	Tools for calibrating your BladderScan instrument. The calibration container has a spiral-shaped target which provides a known reference in a spherical coordinate system. The calibration of the instrument to this known reference increases the accuracy of volume measurements.
Console	The main BladderScan device that provides operating controls and communicates with the user via images and text displays on an LCD screen.
Coupling medium	A substance, such as ultrasound gel, that enhances the transmission of ultrasound waves.
Flashing Aiming Arrows	Indicate the bladder is not inside the scan cone and the Probe needs to be redirected. The arrow shows the direction to move or tilt the Probe to improve the measurement. Re-aiming is required.

Term	Meaning
HIPAA	Health Insurance Portability and Accountability Act, enacted by the US Congress in 1996. Title II of HIPAA, the Administrative Simplification provisions (AS), requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The AS provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the US health care system.
Image cone	During a measurement, this is the cone-shaped area in which the Probe transmits ultrasound waves.
Instrument	In this manual, refers to the BladderScan BVM 9500. The BladderScan instrument transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume and UEBW.
LCD screen	The LCD (liquid crystal display) screen on the BladderScan Console that displays measurement information, instrument status, and other exam settings and information.
NeuralHarmonics® Technology	A patent-pending technology that sharpens accuracy and accelerates speed of three-dimensional ultrasound bladder volume measurements.
Probe	The handheld part of the BladderScan instrument that transmits ultrasound energy to the patient.
Results display	Ultrasound image showing an abdominal cross-section with the bladder shown as a dark circle on a field of speckled gray. Also referred to as B-Mode.
SCAN button	Located on the underside of the BladderScan Probe, this button is used to initiate the measurement.
ScanPoint® image management technology	The software and online service provided by Verathon® that prints exam results, maintains patient records, displays ultrasound images from exams, downloads software updates, and calibrates the BladderScan instrument.
ScanPoint with QuickPrint	ScanPoint with QuickPrint is a software program installed on your computer that communicates with ScanPoint Online to help you quickly and easily download and print download and print exam reports.
Sleep Mode	When the BladderScan instrument powers down to conserve energy. Press the POWER button to turn on the instrument.

Term	Meaning
Solid aiming arrow	Indicates the bladder is inside the scan cone but is not completely centered. The arrow shows the direction to move or tilt the BladderScan instrument to improve the measurement. Re-aiming is optional but not required.
Supine position	Refers to the patient laying on their back.
Suprapubic	The area above the pubic bone.
Symphysis pubis	The front of the pelvis where the pubic bones meet.
UEBW	Ultrasound estimated bladder weight: a measurement of bladder wall mass to help identify bladder outlet obstruction (BOO).
Ultrasonic	Involving ultrasound. Ultrasound is sound at frequencies above the range that can be heard by the human ear.